

**EFFECT OF INTRADIALYTIC STRETCHING EXERCISES ON
MUSCLE CRAMPS AMONG PATIENTS UNDERGOING
HEMODIALYSIS**

**BY
PRIYAKRISHNA**

**A DISSERTATION SUBMITTED TO THE TAMILNADU DR.M.G.R MEDICAL
UNIVERSITY, CHENNAI, IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF MASTER
OF SCIENCE IN NURSING
OCTOBER 2015**

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CRAMPS AMONG PATIENTS UNDERGOING HEMODIALYSIS**

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DECLARATION

I hereby declare that the present dissertation entitled “**An Experimental Study to Assess the Effect of Intradialytic Stretching Exercises on Muscle Cramps among Patients Undergoing Hemodialysis at Apollo Hospitals, Chennai**” is the outcome of the original research work undertaken and carried out by me under the guidance of **Dr.Latha Venkatesan, Msc, (N)., M.Phil (N)., Ph.D (N), M.B.A.,** Principal, Apollo College of Nursing, and **Mrs. Sasikala .D M.Sc (N),** Reader, Medical Surgical dept, Apollo College of Nursing, Chennai – 600 095. I also declare that the material of this has not found in anyway, the basis for the award of any degree or diploma in this university or any other university.

M.SC (N) II YEAR

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SYNOPSIS

An Experimental Study to Assess the Effect of Intradialytic Stretching Exercises on Muscle Cramps among Patients Undergoing hemodialysis at Apollo Hospitals, Chennai

Objectives of the Study

1. To assess the level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
2. To determine the effectiveness of intradialytic stretching exercise on muscle cramp comparing the level of muscle cramps between control group and experimental group of patients undergoing hemodialysis.
3. To assess the level of satisfaction of Patients regarding intradialytic stretching exercises on muscle cramps among experimental group patients undergoing hemodialysis.
4. To find out the association between the selected demographic variables and level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
5. To find out the association between the selected clinical variables and level of muscle cramps among control and experimental group patients undergoing hemodialysis.

The conceptual framework for the study was developed on the basis of King's Goal Attainment Model, which was modified for the present study. An intensive review of literature and experts guidance laid the foundation to the development of tools such as demographic variable proforma, clinical variable proforma, patient satisfaction rating scale.

In this study, true experimental research design was adopted. The present study was conducted at Apollo hospitals, Chennai among clients undergoing hemodialysis with muscle cramp. The sample size for the present study was 60 clients with muscle cramp, among which, 30 clients were randomly assigned to control group and 30 clients to experimental group who satisfied the inclusion criteria.

The investigator used the demographic and clinical variables proforma of patients to obtain the baseline data. Modified numerical pain rating scale was used to assess the level of muscle cramps during hemodialysis and rating scale to assess the level of satisfaction of patients regarding intradialytic stretching exercise. The data collection tools were validated and reliability was established. After the pilot study, the data collection of main study was conducted for a period of 4 weeks. The collected information was tabulated and analyzed by using appropriate descriptive and inferential statistics.

The Major Findings of the Study

- A significant percentage of the patients undergoing hemodialysis were in the age group of 31-35years (33.30%) and >35 years (46.70%), qualified up to higher secondary education (23.3,43.3%) and majority were married (73.3%, 90.0%) in control and experimental group respectively. Most of the patients were male (60.00%, 63.30%), moderate workers (40%,56.6%) with an annual income of <3 lakhs (40.0%), and 3-5 lakhs(43.3%) in control group and experimental group respectively.

- Most of the patients were non vegetarians (66.7%, 63.3%) , non smokers and non alcoholics (40.0%, 40.0%), used analgesics for pain relief (53.3%,53.3%) and had temperature between 98-99f (76.7%, 76.7) in control and experimental group respectively. Majority of the patients' height was >155cm (80%,50%), nearly half of the patients' weight was 56-60kg (53.3%, 50.0%), with systolic blood pressure of 121-130 mm hg (50%) and 111- 120mm hg (43.3%), diastolic blood pressure of 70-80 mm hg (46.7%40%) in both control an experimental group respectively. Nearly half of the patients had urinary disease (43.30%, 50%), hypertension (53.30%, 46.70%) and most of them had no history of cardiovascular disease (63.30%, 56.70%) or diabetic mellitus (63.30%, 60%) in control and experimental group respectively.
- Most of the patients undergoing hemodialysis had moderate level of muscle cramps (53%,57%) in the pre-test, among control and experimental group respectively, whereas in post test most the patients had severe level of muscle cramps (63.33%) in control group and only mild level of muscle cramps (60%) in experimental group.
- The pre test mean scores and standard deviation of muscle cramps is (M=6.13,SD =1.28)in control group and (m=6.6, SD=1.27) in experimental group with t' value -0.403 whereas the post test mean scores and standard deviation of muscle cramps is (M= 6.87, SD= 1.20) in control group and(M= 5.8, SD= 0.65) in experimental group with t' value of 4.86 at P< 0.001 level. Hence the null hypothesis Ho1 “There

will be no significant difference in the pretest and post test scores of muscle cramps between control and experimental group of clients undergoing hemodialysis” was rejected.

- Majority of the patients undergoing hemodialysis in experimental group were highly satisfied with the method application of intradialytic stretching exercise (93.33%), the effectiveness of therapy (90%) and approach of researcher (93.33%).
- There was no significant association between selected demographic variables namely age, gender, educational status, occupation, marital status, nature of work and level of muscle cramps in control and experimental group of patients. Hence the null hypothesis H_02 “There will be no significant association between selected demographic variable and pre -test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.
- There was no significant association between selected clinical variables like weight, height, systolic BP, diastolic BP, history of smoking and alcoholism, type of diet, history of urinary diseases, history of cardiovascular diseases, history of hypertension, history of diabetes etc and level of muscle cramps in control and experimental group of patients. Hence the null hypothesis H_03 “There will be no significant association between selected clinical variable and pre-test level of

muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.

Recommendations

- A similar study could be undertaken on larger scale for more valid generalization.
- This study could be replicated in different settings.
- The study could be conducted to compare different non pharmacological methods of muscle cramp management.
- Pain management protocol with incorporated intradialytic stretching exercise can be made and put in to practice.

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Chapter I
Introduction

CHAPTER I

INTRODUCTION

Background of the Study

“The functional basis of quality of life involves continuous functioning reciprocal interactions between persons and their environment”.

- Alexander and Williams

The crucial areas of human life are physical well being, social activities, personal development, recreation and economic circumstances and these factors largely influence the persons' relationship with environment .To a greater extent, the quality of life led by a human being is influenced by his physical well being. Physical well being depends upon the accurate balance of correspondents like fluid, solutes and even some waste materials. Thus maintenance of volume of the various body fluids is essential to man's survival.

Given unrelenting daily acquisition of food and fluids, preservation of the internal environment requires the continuous excretion of these dietary substances in amounts that balance precisely the quantities acquired by ingestion or metabolic transformation. Although losses from skin, lungs and intestine normally contribute to this excretory capability, kidney are bearing the greatest responsibility for solute and water removal.

Different kidney pathologies challenge these functions and endangers human life . Two such important pathologies are acute and chronic renal failure. But in early years itself, some had the vision and courage to risk everything in search of the answer for treating renal failure and the first clinical dialysis on a uremic man was performed in mid October 1924 by George Hass in Germany.

Hemodialysis is by far the most common method of treatment employed for renal failure. It offers a more rapid change in plasma solute core position within four hours.

Chronic hemodialysis was first introduced in 1960s' to extend the lives of patient with end stage renal disease and by 1982, almost 1,00,000 patients throughout the world were being kept alive by some form of dialysis therapy. Dialysis removes many of the toxins responsible for the uremic syndrome and prolongs survival. However the dialysis treatment does not fully correct the uremia and may be associated with treatment related complications. These complications prevent patients from attaining a state of full health and interfere with many aspects of life. The degree to which an individual patient can adapt to their medical and psychosocial stresses is reflected in the quality of life of that individual.

Non specific physical but a few methods are available to measure their severity. The six most important symptoms of hemodialysis patients are tiredness, muscle cramps, pruritus, dyspnoea , headaches and joint pains. Nurses, patients family and others health care providers share the interest in maximizing positive outcome of hemodialysis. This can be achieved by intervening the patients problems during the procedure. In this study, the investigator is interested to elicit the effect of intradialytic stretching exercises on muscle cramps experienced by the patients during hemodialysis.

Need for the Study

Chronic kidney disease (CKD) is an important non communicable disease epidemic that affects the world population including India. The prevalence of end stage renal disease (ESRD) is rising throughout the developed and developing countries mainly due to diabetes mellitus and hypertension.

CKD will kill 36 million people by the year 2015. In India, 10 lakhs people suffer from kidney failure and more than four crores are at risk (Tamil Naidu kidney research foundation, 2006). In South India, an average of 500 patients register for hemodialysis each year. In government hospital nearly 40-50 patients undergo hemodialysis each day (40% thrice a week, 20% twice a week, others once a week).

Dialysis saves lives. However, dialysis alone can not make those lives active and meaningful. Measures should be employed to improve the physical well being of the patients. Exercise is crucial in the rehabilitation of many individuals with chronic renal insufficiency. Almost all patients complain of muscle cramps at one or other time during dialysis usually of lower extremities that too of calf muscle. They are managed with normal saline infusion, simple calf massages and even by temporarily stopping the ultrafiltration till cramps go off. Some of them are prescribed carnitine preparations regularly for preventing muscle cramps. Non pharmacologic prophylactic measures are not employed.

In early days, physicians were the ones who prepared the equipment for hemodialysis, monitored the patient and terminated the treatment. It was not long before physicians began to rely on nurses to perform most of the patient care

decisions doing entire hemodialysis. Currently nurses carryout 20 to 100% of the technical functions. This reveals the high responsibility and multiple roles (caregivers, advocate, technical supervisor etc.) relying on the nurse.

Patients on chronic maintenance hemodialysis are confronted with several complications related to the treatment. Muscle cramps being among the most common complaint is estimated to occur in up to 20% of hemodialysis sessions. Lee (1999) quoted in dialysis and transplantation journal that in a specific study involving 14,000 hemodialysis treatments on 103 patients the cumulative incidence of cramps was estimated to be 86 %. Muscle cramps are prolonged involuntary muscle contractions. To relieve an established cramp, one must passively stretch the contracting muscle. Prophylactic stretching of the particular muscle can also prevent attacks.

Since cramps are a common intradialytic event, the discomfort leads to premature termination of the treatment, non compliance with the prescription and therefore underdialysis. Thus interfering with the muscle cramps and even preventing the occurrence become a major responsibility of the personal in charge of the patients. Since nurses are taking care of hemodialysis patients almost everywhere, it becomes predominantly the nurses role.

However, only a few patients are able or willing to participate in exercises training and stretching which is organized on an outpatient basis. As a consequence, exercise programmes are thought to be better incorporated into the dialysis seivone. But in case of stretching exercises, the patient positions in bed during dialysis prevent self stretching. Thus the investigator has opted to provide passive calf stretching exercises prophylactically during hemodialysis to relieve or

prevent muscle cramps. Based on the reviews of literature and the investigator's personal clinical experience in dialysis unit, the researcher found many of the patient developed muscular cramps. So the investigator was interested to find the effective of prophylactic intradialytic passive calf stretching exercises in minimizing the muscle cramps during hemodialysis.

Statement of Problem

An Experimental Study to Assess the Effect of Intradialytic Stretching Exercises on Muscle Cramps Among Patients Undergoing Hemodialysis at Apollo Hospitals, Chennai.

Objectives of the Study

1. To assess the level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
2. To determine the effectiveness of intradialytic stretching exercise on muscle cramp comparing the level of muscle cramps between control group and experimental group of patients undergoing hemodialysis.
3. To assess the level of satisfaction of patients regarding intradialytic stretching exercises on muscle cramps among experimental group of patients undergoing hemodialysis.
4. To find out the association between the selected demographic variables and level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
5. To find out the association between the selected clinical variables and level of muscle cramps among control and experimental group patients undergoing hemodialysis.

Operational Definitions

Effect

In this study it is the result of intradialytic stretching exercises on muscle cramps after administration to patients during hemodialysis as measured by comparing the level of muscle cramps between experimental and control group patients.

Intradialytic Stretching Exercises

In this study it refers to the passive exercise performed by the investigator for the gastrocnemius and soleus (calf) muscle during the end of second hour, stretching exercise for calf muscles such as Flexion and Extension of angle for five times, flexion of knee and hip joint at 90° for five times, flexion of hip 90° and knee joint >90° for five times and all the three steps should to be repeated every fifteen minutes, from the end of second hour of dialysis till the completion of the dialysis. It helps in improving efficacy of dialysis by increased perfusion of skeletal muscles.

Muscle Cramps

In this study it refers to painful involuntary spasms or contraction associated with severe muscle cramps of the calf muscles of patients during hemodialysis, as reported by the patients and measured by numerical pain rating scale developed by McCaffery et al (2000). That occur frequently in patients receiving dialysis.

Hemodialysis

In this study it is a treatment employed for patients with renal failure for rapid change of plasma solute composition within four hours. In hemodialysis,

blood is removed from the body and filtered through a man made membrane called a dialyzer, or artificial kidney, and then the filtered blood is returned to the body.

Assumptions

This study assumes that,

- Hemodialysis results in sodium depletion in muscles. It causes spasm of calf muscle , arms and hands. Spasm of muscle cause severe cramps or pain .
- Calf muscle exercise improves perfusion.
- Exercise involves stimulation of muscles, bones and nerves.
- Improve perfusion help to relieves the spasm of the muscle.

Null Hypotheses

The study assumes that,

- Ho1:** There will be no significant difference between pretest and post test scores of muscle cramps in control and experimental group of patients undergoing hemodialysis.
- Ho2:** There will be no significant association between selected demographic variables and pre -test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis.
- Ho3:** There will be no significant association between selected clinical variables and pre-test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis.

Delimitations

The study was limited to

- adult patients undergoing hemodialysis
- a period of 4 weeks of data collection.

Conceptual Framework for the Study

Conceptual framework deals with the concepts that are assessable together in some rational scheme by virtue of their relevance to a common theme (Polit and Beck, 2012). Conceptual framework for present is based on king's goal attainment theory. According to Imogene king, nursing is defined as a process of action, reaction and interaction where nurse and clients share information about their perception. Through perception and communication they identify problems, through which they set goals and take necessary actions. King goal attainment theory is based on the concepts of personal, interpersonal and social system including perception, judgment, action, reaction, interaction and transaction and perception.

Perception

A person imports energy from the environment and transforms, processes and stores it. The study assumes that there is interpersonal relationship between the nurse, investigator and participants. The Nurse investigator perceives that there is a need for the development of an alternative nursing care like intradialytic stretching exercises for patient undergoing hemodialysis to reduce the level of pain perception during muscle cramps and assessed using standardized pain assessment scale.

Judgment

Analyzes the areas of action to be carried out. In this study the nurse investigator judges that intradialytic stretching exercises for hemodialysis patients reduces the level of pain perception of the patients during muscle cramps. Thus the researcher takes decision to implement the intradialytic stretching exercises.

Action

Individual experts the perceived energy, as demonstrated by observable behavior by taking mental or physical activity, nurse investigator takes action by the development of intradialytic stretching exercises for hemodialysis patients for relieve patients from level of pain perception during muscle cramps.

Reaction

Reaction is the experience or outcome that is expected as a part of goal attainment. The intradialytic stretching exercises in experimental group clients were highly satisfied. The nurse investigator makes the arrangement for disseminating the information regarding intradialytic stretching exercises and turn the patients were benefited.

Interaction

Refers to verbal and non-verbal behavior between an individual and the environment or among two or more individuals. It involves goal directed perception and communication. Actions lead to interaction where the nurse investigator executes her intradialytic stretching exercises upon the level of pain associated with hemodialysis the patients muscle cramp level is reduced.

Transaction

Imogene king says that transaction is two individuals mutually identify goals and means to achieve them. They reach an agreement about how to attain these goals and these about to realize them. In this study subjects from the experimental group shows highly satisfactory in reduction in the level of muscle cramp through intradialytic stretching exercises and developed no complications.

Feed back

Outcome may either be satisfactory or unsatisfactory. Satisfactory shows the effectiveness of intradialytic stretching exercises and reduction in the level of muscle cramps and for unsatisfactory the activity is planned again. In this study investigator appraise the level of satisfaction about intradialytic stretching exercises through rating scale, if the therapy is satisfactory it can be disseminated and to the control group too. If unsatisfactory the activity is planned again or other best method is adopted.

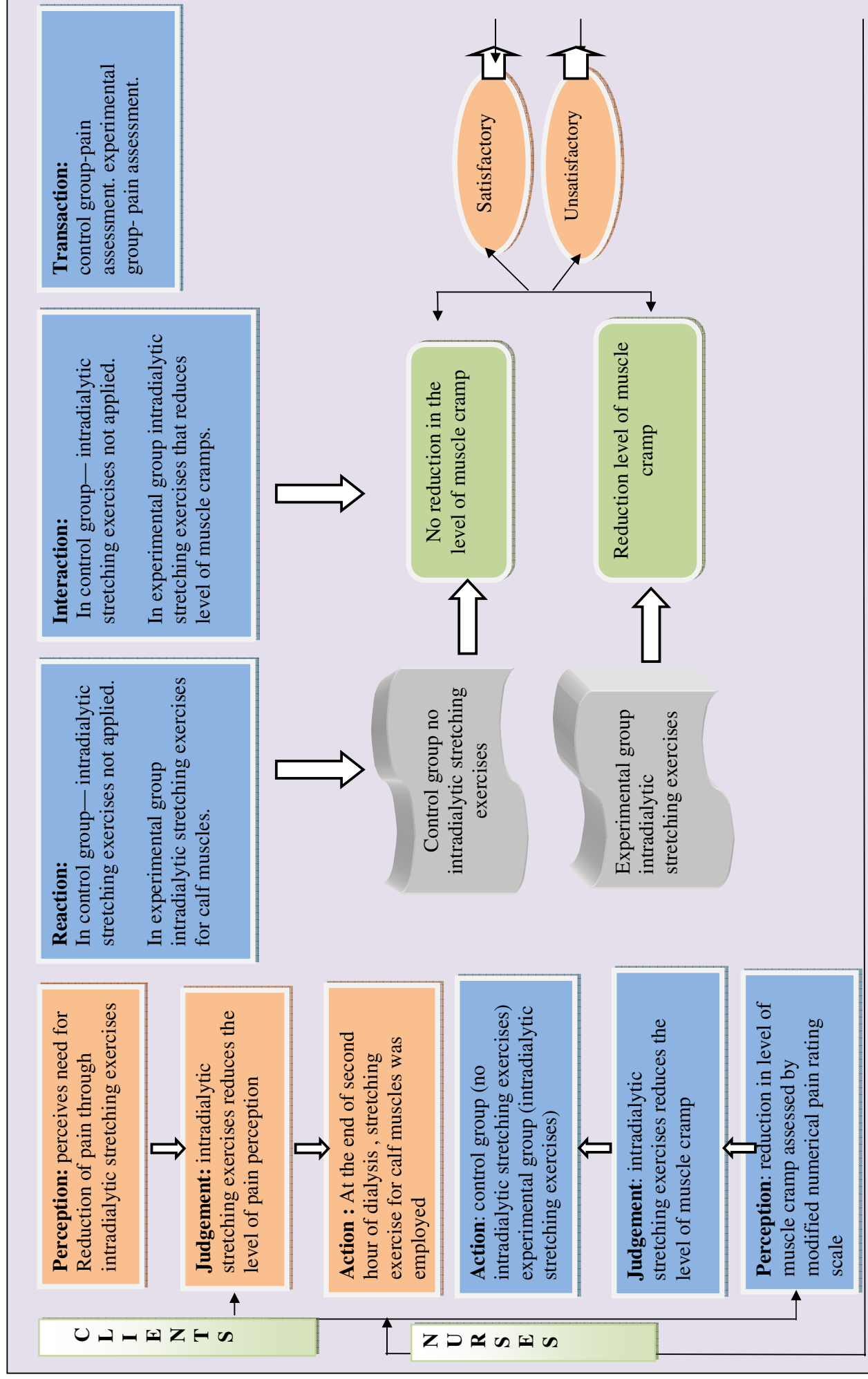


Fig 1: Conceptual Framework Based on modified Kings Goal Attainment Theory

Projected Outcome

The study will be helpful in obtaining evidence for the nurse in controlling the pain perception for the patients who receiving hemodialysis.

Summary

This chapter has dealt with the background of the study, need for the study, and statement of the problem, objectives, operational definitions, hypothesis, assumptions, delimitations and conceptual framework.

Organization of the Report

Further aspects of the study are presented in the following five chapters.

In Chapter – II : Review of literature

In Chapter – II : Research methodology includes research approach, research design, setting, population, sample and sampling techniques, tool description, content validity and reliability of tools, pilot study, data collection procedure and plan for data analysis.

In Chapter – IV : Analysis and interpretation of data

In Chapter – V : Discussion

In Chapter – VI : Summary, conclusion, implications and recommendations.

Chapter II

Review of literature

CHAPTER II

REVIEW OF LITERATURE

The task of reviewing research literature involves the identification, selection, critical analysis and written description of existing information in the topic of interest. In this chapter, an attempt has been made to bring out the available literature which helped in projecting the widened perspective of the study.

- **Literature related to hemodialysis.**
- **Literature related to muscle cramps among patients undergoing hemodialysis.**
- **Literature related to the effectiveness of physical exercises on muscle cramps among patients undergoing hemodialysis.**

Literature Related to Hemodialysis.

Thirty samples were selected and analysis were done thrice a week in a prospective study analysis by Saraswathy et al (2012) on economic evaluation of end stage of renal disease patient undergoing hemodialysis at Amrita institute of medical science, Kerala. The study reveals that total cost per session was found to be around Rs.4500. Fifty six percent contributes direct medical cost whereas 20% contributes direct non medical cost. Hence these kind of pharmacoeconomic studies are important to find out the impact of cost of hemodialysis on patient suffering from end stage renal disease.

Ilayabharthi (2012) conducted a cross sectional study on predictors of quality of hemodialysis patients in India. Seventy eight samples were analyzed for

two months. Demographic, nutritional, functional subjective global assessment and kidney disease quality of life (kdqol-36) assessments were done. Hence patients with higher urine output had better physical performance and had higher degree of protein energy malnutrition.

Cross sectional cohort study was conducted by Chistopher et al (2006) to assess skeletal muscle wasting among patients with chronic kidney disease (CKD) at stages 4 and 5, on hemodialysis (HD) and peritoneal dialysis (PD). One hundred and thirty four patients were selected and divided into three groups like sixty hemodialysis, twenty eight peritoneal dialysis and forty six chronic kidney disease at stage four and five. Functional assessment was done by sit to stand test. The study reveals that serum phosphate and calcium-phosphate product was high in hemodialysis patients when compared to chronic kidney disease patients in stage four. There is no significant difference when comparing patients undergoing peritoneal dialysis with chronic kidney disease patients in stage four. Hence chronic kidney disease patients in stage five showed significant difference in muscle wasting than the chronic kidney disease patients in stage four who were undergoing both the dialysis treatment and these kind of patients were recommended for exercise programmes.

Literature Related to Muscle Cramps.

The frequency of symptomatic muscle cramps decreased by 60% in the creatine monohydrate treatment group during the treatment period in a cross sectional study on hemodialysis patients conducted by Bass, (2011). This decreasing incidence of muscle cramps disappeared in the washout period in the creatine group. There was no difference in the incidence of muscle cramps in the

placebo group. The haematocrit, Kt/V, serum albumin, and haemodynamics remained unchanged in both groups during the treatment and washout periods. Serum creatinine increased slightly after creatine monohydrate treatment. No adverse effect was found in either group during the treatment and washout period. These data suggest that creatine monohydrate can reduce the incidence of HAMC and that it may be a safe agent.

Catto et al (2011) conducted a study to see the effect of a slowly released oral preparation of sodium chloride (Slow Sodium) on the frequency and severity of muscle cramps, on blood pressure, and on body weight which was compared with that of placebo in a double-blind cross-over trial in 19 patients on maintenance hemodialysis for end-stage renal failure. A significant reduction in both the frequency and severity of cramps was found while the patients were receiving the sodium chloride preparation and no significant alteration in blood pressure or body weight was detected.

In a prospective longitudinal study on exercise program to enhance physical performance and quality of life of older hemodialysis patients at university of Toronto, convenient sampling was used to select nine participants were participated in the study. Exercise programme was performed for three weeks and measured by duke activity index. The study reveals that patients showed a gradual increase in the amount of exercise performed over 12 weeks. Hence these exercise program showed benefits in the improvement of quality of life. Gerald et, al (2010)

Seventy two patients were selected to receive either intradialytic exercise training or home based training or usual care in a randomized controlled trial on intradialytic versus home based exercise training among hemodialysis patients at renal research centre, Australia. The interventions were given for six months Kirsten, et al. (2009). The study reveals that home based training are more cost effective training program in hemodialysis patients. Hence home based training has more benefits than the intradialytic training program.

Brass, et al , (2002) had studied 122 patients on maintenance hemodialysis. Peripheral arterial disease was determined by measurement of ankle-brachial index pre and post dialysis, in lower extremities. Intradialytic cramps experience was assessed from history, 52.1% patients reported intradialytic cramps. Old age people were only 37.5% and it was inferred that there was no relationship between cramps during dialysis and peripheral arterial disease.

Pratecpavanich (1999) studied 24 patients with nocturnal calf cramps. They are divided into two groups to quantitatively compare the effect of trigger point injection and oral quinine. The study was conducted for four weeks and followed up to after four weeks of the study. Parameters were cramp frequency, duration, pain intensity and cramp index, the outcome of all measures were found to be significantly better in group treated with trigger point injection. Result supported that gastrocnemius trigger point was one cause of nocturnal calf cramps.

Forty six complete dialysis treatment sessions, was studied by Dial (2000). Electromyographic (EMG) activity was recorded from a leg muscle in patients who had cramps. The results indicated that the mean muscle cramp latency from

start of dialysis was 248 minutes and average cramp was 10 minutes in duration. Also tonic electromyographic activity in patients with muscle cramps showed a continued increase throughout the latter part of dialysis. This suggested that increase in electromyographic activity might be casually related to muscle cramps.

Literature Related to the Effectiveness of Physical Exercises on Muscle Cramps.

In Bollineni superspeciality hospital, Raj (2009) conducted a study to assess the high frequency of primary failure of intradialytic stretching exercises. The sample was of 75 patients (44 M, 31 F) with a recent diagnosis of ESRD underwent intradialytic stretching exercises. The results were primary intradialytic stretching exercises failure was detected in 18 (24%) of patients. When presence of postoperative thrill on intradialytic stretching exercises was added to analysis they found that of primary intradialytic stretching exercises Failure.

A study was conducted by Athens (2005) in Greece to evaluate intradialytic stretching exercises . All cases of intradialytic stretching exercises applied in hemodialysis in two HD units that use the same treatment protocols were recorded within the last 3 years. The results revealed that intradialytic stretching exercises is a safe, non-invasive and effective method for the management of muscle cramps.

Stores et al (2005) studied 12 maintenance hemodialysis patients by providing them incremental and constant work rate cycle exercises for 6-8 wks and found out that eight weeks of leg cycling during hemodialysis in maintenance patients improves not only cardiopulmonary fitness and endurance but also muscle strength, muscle power fatigability and physical function. The study suggested that

exercises during dialysis treatment was safe and consented either better psychosocial performance or better dialytic efficiency.

In year 2004 Banerjee et al studied two groups of 10 patients in each by exercising them submaximally using a stationary cycle during isovolemic dialysis for 10 minutes rest and again 10 minutes of exercises. Cardiac output, periplenal resistance, blood volume and stroke volume were measured using ultrasound dilution and concluded that the hemodialysis response to exercises during hemodialysis is comparable with that in normal individuals.

Thirty two hemodialysis patient participated in a progressive self faced exercise programme including cycling before or during hemodialysis or walking on treadmill before hemodialysis. Patients also had the option of doing stretching and light weight exercises during hemodialysis. They were assessed after a duration of 3.6and 12months of participation for physical strength, weight, blood pressure, electrolytes, hematocrit, glucose and intradialytic cramping. Result showed that all patients had improvement in measures of physical performance. (Cappy et al ,1999).

A quasi experimental one group pre and post test design study conducted by Ridley et al (1999). Eight subjects completed a 12 week excise programme involving warm-up, stretching , strengthening and cardio vascular training. The result demonstrated improvements in participants, physical capacity, quality of life and ability to perform activities of daily living. They concluded that an exercise during dialysis, programme was safe and had the potential to result in positive patient outcomes.

A cross sectional study was conducted by Jeromy (2012) in the University of Maryland Baltimore, USA to assess the prevalence of intradialytic stretching exercises in incident hemodialysis patients. Correlation with patient factors that may be associated with maturation failure. The sample was 195,756 adult patients initiating outpatient hemodialysis therapy in the United States between July 1, 2005, and December 31, 2009, with 6 months or more prior nephrology care. Their results revealed that intradialytic stretching exercises use varied from 19.0% (very high risk) to 25.6% (low risk). In a model using only these risk categories, logistic regression showed lower ORs for moderate-, 0.90 (95% CI, 0.88-0.93); high-, 0.80 (95% CI, 0.78-0.83); and very high-risk patients, 0.68 (95% CI, 0.63-0.73) compared with low risk. In conclusion they added that clinical risk factors identified have limited ability to predict incident intradialytic stretching exercises use. Even patients judged at highest risk can have successful intradialytic stretching exercises construction and initiate dialysis therapy through a functioning intradialytic stretching exercises.

Susanne, (2012) conducted a phenomenographic study on patients perspectives on the implementation of intradialytic cycling at Stockholm, Sweden. Eight samples were selected for the study by purposive sampling technique. The intradialytic cycling was consisted of 30 minutes of cycling at an intensity of 13-15 on the ratio of perceived exertion. The study reveals that the implementation of intradialytic cycling was experienced as positive. Hence, identification of motivators in direct care is important to improve the standards of intradialytic cycling.

Summary

This chapter has dealt with the literature related to hemodialysis , literature related to muscle cramps among patient undergoing hemodialysis, literature related to the effectiveness of physical exercises on muscle cramps among patient undergoing hemodialysis. The literature presented here was extracted from Medline, journal and Wikipedia. It includes fifteen primary sources and four secondary sources. It helped the researcher to understand the prevalence and impact of the problem under the study. It has also enabled the investigator to design the study, develop the tool, plan the data collection procedure and to analyse the data.

Chapter III

Research Methodology

CHAPTER III

RESEARCH METHODOLOGY

Research Methodology is a scientific and systematic way to solve problems. The methodology may differ from problems to problem. Research methodology deals with the research methods and takes into consideration the logic behind the method, we use. It is a significant part of the research under which researcher is able to project a blue print of the research undertaken.

The study was conducted to assess the effectiveness of Intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis. This chapter deals with the research approach, research design, setting, population, sample, sampling technique, sampling criteria, selection and development of the instrument, validity and reliability of the instrument, pilot study, data collection procedure and plan for data analysis.

Research Approach

Research approach is the most significant part of any research. The appropriate choice of the research approach depends on the purpose of the research study which is undertaken.

According to Polit and Beck (2008) experimental research is an extremely applied form of research and involves in finding out how well a programme, product, practices or policy is working. Its goal is to assess or evaluate the success of the program.

An experimental research is generally applied where the primary objective is to determine the extent to which a given treatment meets the desired results.

To accomplish the objective of the study, an experimental approach was considered most appropriate, since the researcher wanted to assess the effectiveness of Intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis.

Research Design

According to Polit and Beck (2008), a research design is the overall plan for addressing a research questions, including specification for enhancing the study's integrity.

True experimental design was used for the study. A true experimental design has the characteristics features as manipulation, control and randomization. Randomization was carried out to select 60 samples and to assign them in the control and experimental groups. Intradialytic stretching exercises was given as manipulation in the experimental group.

In this study two group pre test -post test design was adopted. The researcher has assessed the level of muscle cramps for selected patients undergoing hemodialysis using pain scale for both control group and experimental group before therapy and then manipulated the independent variables i.e. by the application of muscle stretching exercises only to experimental group of patient undergoing hemodialysis. The effectiveness of stretching exercises on dependent variables i.e. the level of muscle cramp was assessed after the therapy. Then the

level of satisfaction on intradialytic stretching exercises was assessed using pain rating scale among experimental group.

The research design is represented diagrammatically as follows

R - O1 X O2

R - O1 O2

R - Randomization

O1 - Pre-test (muscle cramp score)

X - Intradialytic stretching exercises

O2 - Post-test (muscle cramp score)

Research Variables

Variables is anything that can change or anything that is liable to vary.

Independent Variables

The variables that is believed to cause or influence the dependent variables is called independent variables. In this study muscle stretching exercise is the independent variable.

Dependent Variable

The variables hypothesized to depend on or be caused by independent variable is the dependent variable. Muscle cramps is the dependent variable in the study. The level of muscle cramp is assessed at the end of the second hour of a four hour of hemodialysis session.

Extraneous Variables

The variables that confounds the relationship between the independent variable and dependent variables and that need to be controlled either in the

research design or through statistical procedures in the extraneous variables. Demographic variables such as age, sex, education, occupation, nature of work etc. Clinical variable such as weight, height, systolic BP, diastolic BP, history of smoking and alcoholism, type of diet, urinary diseases, cardiovascular diseases, hypertension, diabetes etc are extraneous variables.

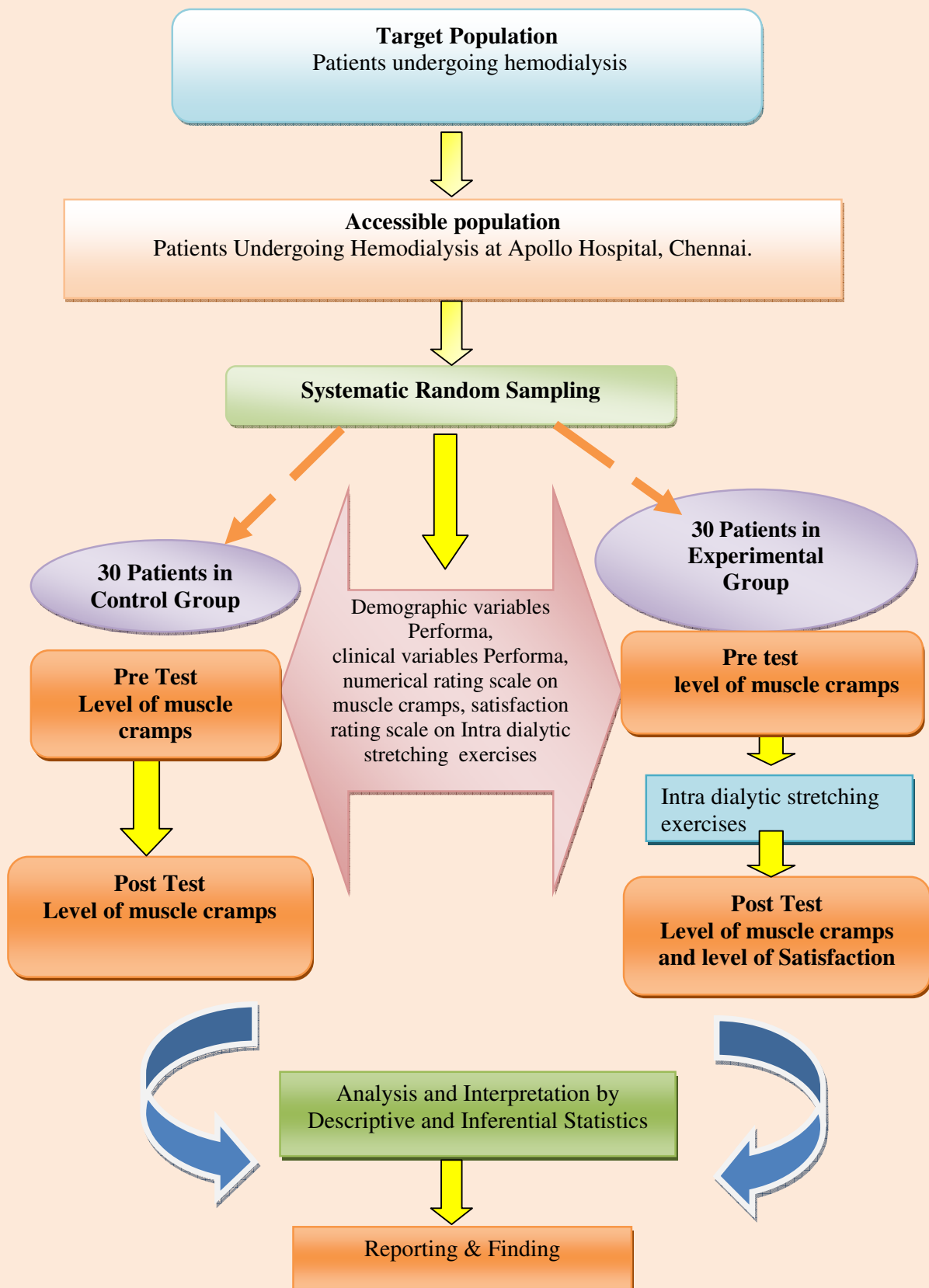


Fig :2 Schematic representation of the research methodology

Setting of the Study

The settings are the more specific places where data collection will occur. The study will be conducted in 1200 bedded multi speciality Apollo main hospitals at Greams road and 350 bedded Apollo specialty hospitals at Vanagaram, Chennai. Apollo main hospitals at Greams road has 30 bedded dialysis unit and Apollo specialty hospitals at Vanagaram has 5 bedded dialysis unit. An average of 50 to 60 patients per day come for dialysis.

Population

Population is the entire aggregation of cases which meet designated set of criteria. The **Target population** is the group of population the researcher aims to study and to whom the study findings was generalized. The **Accessible population** is the aggregate of cases that conform to designated criteria and that are accessible as subjects for a study.

In this study target population was the patients undergoing hemodialysis in the hemodialysis units at Apollo hospitals, Chennai.

In this study accessible population was the patient undergoing hemodialysis with muscle cramp in Apollo main hospitals and Apollo specialty hospitals, Chennai.

Sample

Sample consist of subset of units that comprises of the population. (Polit & Beck, 2010) satisfying the inclusion and exclusion criteria. A sample of 60 patients undergoing hemodialysis was selected, among them 30 patients were randomly assigned to the control group and 30 patients were assigned to the experimental group..

Sample Size

The sample consisted of 60 patients who are undergoing hemodialysis. Among them 30 in control and 30 in experimental group were allotted.

Sampling Technique

The technique adopted for this study is systematic random sampling technique. The selected patients were randomly assigned to control and experimental group by lottery method . The patients who got odd number in the lottery were assigned to experimental group and patients who got even number in the lottery were assigned to control group.

Criteria for Sample Selection

Inclusion Criteria

Patients undergoing hemodialysis who are

- in the age group 20-60 yrs.
- could understand either Tamil or English.
- were willing to participate.
- underwent hemodialysis for a duration of minimum four hours.

Exclusion Criteria

Patients with chronic kidney diseases undergoing hemodialysis who are

- undergoing emergency hemodialysis.
- having femoral catheter.
- having any lower limb pathology.
- having diabetic neuropathy.
- having psychiatric or neurological problem.

- having altered level of consciousness.

Selection and Development of Study Instruments

The study aimed at evaluating the effectiveness of intradialytic muscle stretching exercises on muscle cramps.

Data collection instruments are developed through extensive review of literature and consultation with experts and guidance of faculty members. Instruments used in this study were demographic variables proforma, clinical variables proforma, 0-10 numeric pain rating scale, rating scale for level of satisfaction regarding intradialytic stretching exercise.

Demographic Variables Proforma of the Patients Undergoing Hemodialysis

Demographic variables proforma includes age, sex, education, occupation, nature of work etc.

Clinical Variables Proforma of the Patients Undergoing Hemodialysis

Clinical variables proforma includes weight, height, systolic BP, diastolic BP, history of smoking and alcoholism, type of diet, urinary diseases, cardiovascular diseases, hypertension, diabetes etc.

Modified Numerical Pain Rating Scale.

To assess the severity of muscle cramps, modified numerical pain rating scale had been used.



Score interpretation

The modified numerical pain rating scale scores were interpreted as follows.

Score	Intensity of cramps
0	None
1 – 3	Mild
4 – 7	Moderate
8 – 10	Severe

Level of Satisfaction Rating Scale regarding intradialytic stretching exercises.

The patients' satisfaction on intradialytic stretching exercises was assessed by using rating scale. which comprises of 3 categories the effects of the therapy, the method of intradialytic stretching exercises and the approach of the researcher. This rating scale includes maximum score of 10. They are highly satisfied (score = 4), moderately satisfied (score =3), just satisfied (score=2) and dissatisfied (score=1).

Score Interpretation

4-10	25%	-	Dissatisfied
11-20	26 - 50%	-	Just Satisfied
21-30	51- 75 %	-	Moderately satisfied
31-40	>75%	-	Highly satisfied

Psychometric Properties of Instrument

Validity of the instruments

Content validity was established by getting opinion from many experts in the field of medical surgical nursing. Three of the experts were nursing personnel and one biostatistician. The evaluators have suggested some specific modification in the objectives and rating scale. The modification and suggestion of experts were incorporated in the final preparation of the rating scale to assess the level of satisfaction of dialysis patients.

Reliability of Study Instruments

The reliability of the tool modified numerical pain rating scale was elicited by using the inter rater technique, Karl Pearson is computed to find out the reliability. The 'r' value for pain scale is 0.9 which shows positive correlation it indicates that the tool are highly reliable. The 'r' value for the standardized numerical pain rating scale was 0.94.

Pilot Study

Polit and Hungler (2004) states that pilot study is administration of some parts of actual study in which the instruments are administered to the subjects to draw from the same population. It is a small scale version or trial run to prepare for a major study. The purpose is to find out the feasibility and practicability of the study.

Pilot study was conducted in Apollo specialty hospital, Chennai, from 25th June to 8th July 2014 November. Thirty samples were assigned in control (15)

and experimental group (15) by systematic random sampling. The data were collected using demographic variables, clinical variables, numerical pain rating scale. First introducing the sample patients, explained the objectives of the study and consent was taken from the participants of the study. Each person was interviewed to gather information regarding patient variables before dialysis began. At the end of second hour, stretching exercise for calf muscles were employed for experimental group prophylactically ensuring privacy. On the other hand, control group patients were not given the intervention. During the next 2 hours muscle cramps severity was assessed in both the control and experimental group. The intensity was rated using numerical pain rating scale. After the pilot study, it was found to be feasible and effective and the study instruments were found to be appropriate.

Protection of Human Rights

The study was conducted

- After approval of ethical committee of Apollo hospitals.
- After obtaining permission from Principal of Apollo college of Nursing, HOD of Medical and Surgical nursing.
- After obtaining written consent from the participants.
- confidentiality was maintained throughout the study.

Plan for Data Collection Procedure

- After obtaining consent from the authority of hospital committee chair persons i.e. chairman and also from head of the department of Nephrology data was collected.

- After getting the consent study participants were selected using systematic random sampling method.
- Administration of demographic and clinical variables performed for experimental and control group clients undergoing hemodialysis.
- Eligible patients were identified by the researcher and selected using purposive sampling technique based on inclusion criteria. The selected patients were randomly assigned to control and experimental group by lottery method .
 - ❖ Odd number samples were for experimental group.
 - ❖ Even number samples were for control group.

Then the data was collected accordingly using the predetermined tools. Each person was interviewed to gather patient variables before dialysis began. At the end of second hour, stretching exercise for calf muscles were employed for experimental group prophylactically ensuring privacy. Control group patients were not given the intervention. During the next 2 hours both the control and experimental groups were assessed for muscle cramps using the numerical pain rating scale.

Intervention protocol

The passive exercise performed by the investigator for the gastrocnemius and soleus (calf) muscle during the end of second hour, stretching exercise for calf muscles such as Flexion and Extension of angle for five times, flexion of knee and hip joint at 90° for five times, flexion of hip 90° and knee joint >90° for five times to be repeated every fifteen minutes from the end of second hour of dialysis

till the completion of the dialysis. It helps in improving efficacy of dialysis by increased perfusion of skeletal muscles.

Plan for Data analysis

The collected data was grouped and analyzed using descriptive and inferential statistics. Descriptive methods used were frequency, percentage, mean, standard deviation. Inferential statistics used were paired and independent 't' test to assess the effect of intradialytic stretching exercises on muscle cramps. chi-square test will be used to determine the association between muscle cramps and patients variables

Summary

This chapter dealt with selection of research approach setting population, sample size, sample technique, sample criteria, selection and development of the instrument validity, data collection procedure and plan for data collection.

Chapter IV
Analysis and Interpretation

CHAPTER IV

ANALYSIS AND INTERPRETATION

Data analysis is conducted to reduce, organize and give meaning to the data. The results obtained from data analyses require interpretation to be meaningful. Interpretation of data involves examining the results from data analysis forming conclusions, considering the implications for nursing, exploring the significance of the findings and suggesting further studies (Polit & Beck, 2012).

This chapter deals with analysis and interpretation of data including both descriptive and inferential statistics. The data were analyzed according to the objectives and hypothesis of the study. Analysis of the data was compiled after all the data was transferred to the master coding sheet. The data were analyzed, tabulated and interpreted using appropriate descriptive and inferential statistics.

Organization of Findings

The findings of the study was organized and presented under the following headings.

- Frequency and percentage distribution of selected demographic variables of the control and experimental group of patients undergoing hemodialysis
- Frequency and percentage distribution of clinical variables of the control and experimental group patients undergoing hemodialysis.

- Frequency and Percentage Distribution of Level of Muscle cramps Perception After intradialytic stretching exercises in the Control and Experimental Group of patients Undergoing Hemodialysis.
- Comparison of mean and standard deviation of level of muscle cramps between control and experimental group of patients undergoing hemodialysis.
- Frequency and percentage distribution of level of satisfaction scores of intradialytic stretching exercises among the experimental group of patients undergoing hemodialysis.
- Association between the selected demographic variables and the level of muscle cramps among the control and experimental group of patients undergoing hemodialysis
- Association between the selected clinical variables and the level muscle cramps among control and experimental group of patients undergoing hemodialysis.

Table. 1

Frequency and Percentage Distribution of Selected Demographic Variables of the Control and Experimental Group of Patients undergoing Hemodialysis.

Demographic Variables	Control Group (n=30)		Experimental Group (n=30)	
	f	%	f	%
Education				
No formal education	5	16.7	0	00.0
Primary School	5	16.7	1	3.3
High school	6	20.0	13	43.3
Higher secondary	7	23.3	13	43.3
College and above	7	23.3	3	10.0
Occupation				
Student	0	00.0	0	00.0
Unemployed	5	16.7	3	10.0
Government	5	16.0	3	10.0
Private	11	36.7	13	43.3
Business	9	30.0	11	36.7
Nature of work				
Sedentary	6	20.0	9	30.0
Moderate	12	40.0	17	56.7
Heavy	12	40.0	4	13.3
Marital status				
Married	22	73.3	27	90.0
Unmarried	7	23.3	3	10.0
Widow	0	00.0	0	00.0
Divorce	1	3.3	0	00.0

Table1 depicts that significant percentage of the patients undergoing hemodialysis were qualified up to higher secondary education (23.3,43.3%), moderate workers (40%,56.6%) and majority were married (73.3%, 90.0%) in control and experimental group respectively.

Fig: 1 suggest that significant percentage of the patients were in age group of 31-35years(33.30%), in control group and >35 years (46.70%), in experimental group.

Fig: 2 suggest that most of the patients were male (60.00%, 63.30%), in control and experimental group respectively.

Fig: 3 depicts that significant percentage of the patients were having an annual income of <3 lakhs (40.0%), in control group and 3-5 lakhs(43.3%) in experimental group respectively.

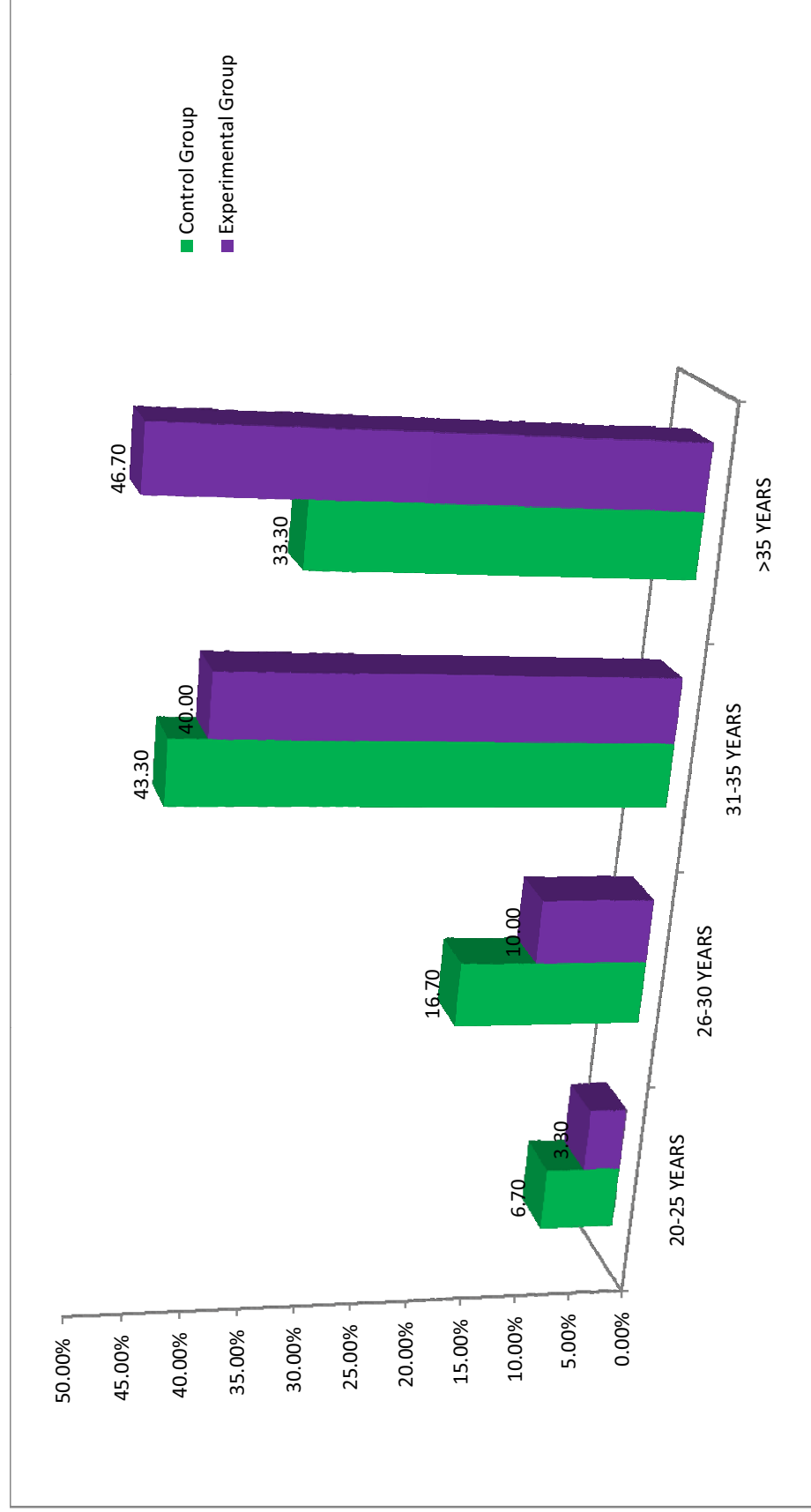


Fig.3 Percentage Distribution of Age among control and experimental group of patients undergoing hemodialysis.

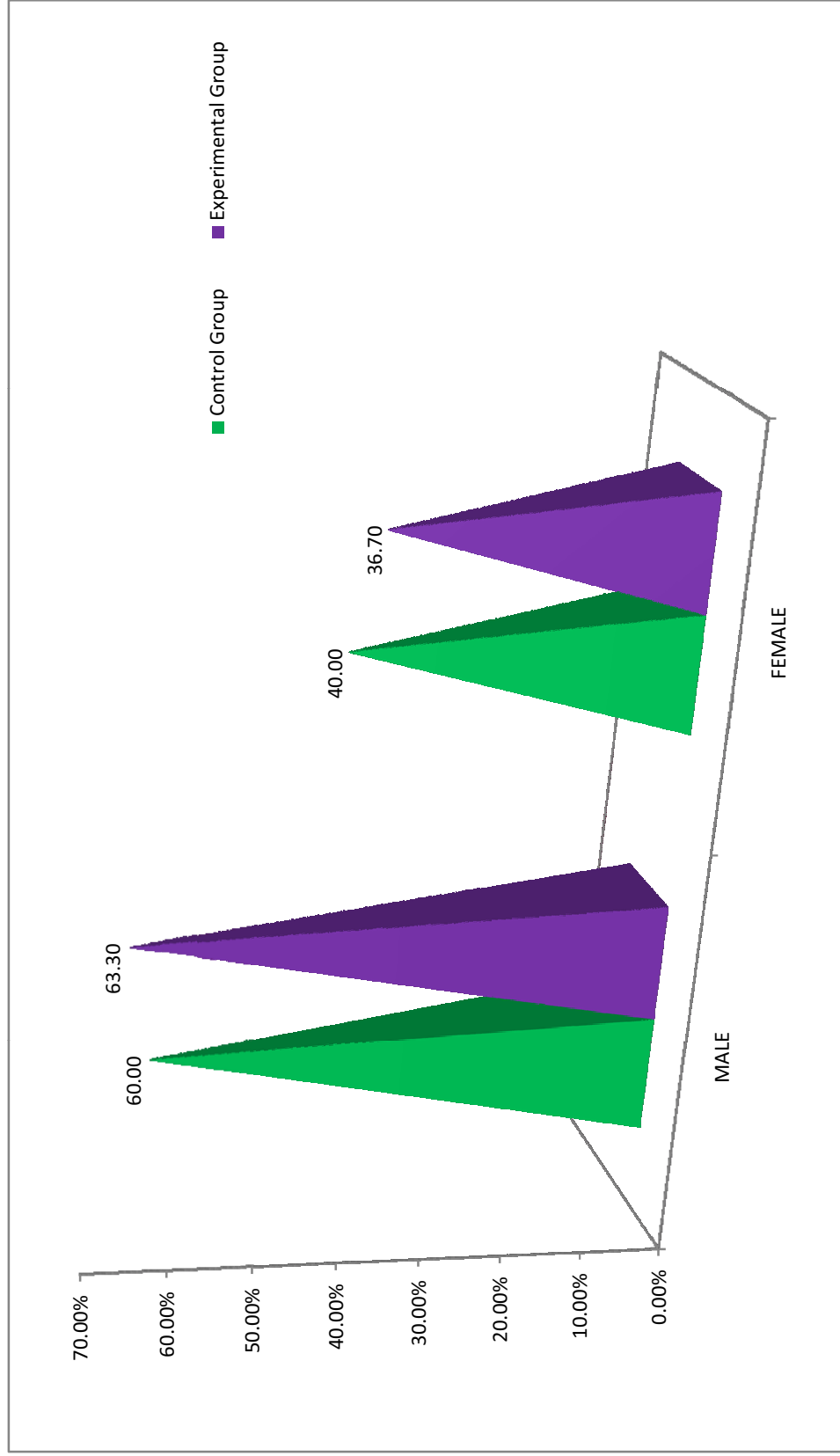


Fig.4 Percentage Distribution of Gender among control and experimental group of patients undergoing hemodialysis.

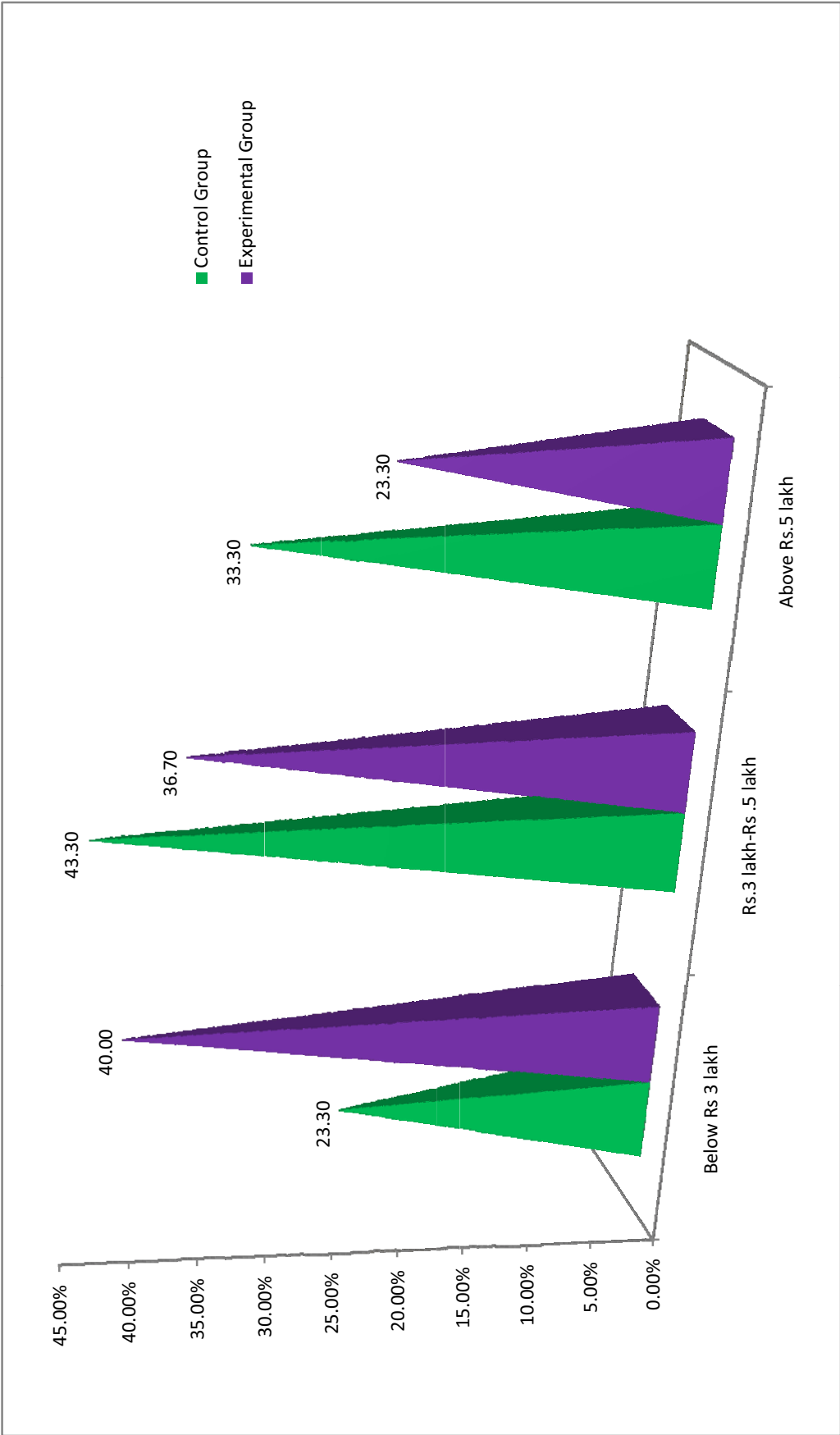


Fig.5 Percentage Distribution of Annual Income among control and experimental group of patients undergoing hemodialysis.

Table .2

Frequency and Percentage Distribution of Clinical Variables of the Control and Experimental Group of Patients Undergoing Hemodialysis.

Clinical Variables	Control Group (n=30)		Experimental Group (n=30)	
	f	%	f	%
History of smoking and alcoholism				
Smoking	1	3.3	7	23.3
Alcoholism	9	30.0	8	26.7
Both	8	26.7	3	10.0
No	12	40.0	12	40.0
Type of diet				
Vegetarian	10	33.3	11	36.7
Mixed	20	66.7	19	63.3
Medication				
Antibiotics	6	20.0	6	20.0
Analgesics	16	53.3	16	53.3
Others	8	26.7	8	26.7
Height				
< 135	0	00.0	0	00.0
136 -140	0	00.0	0	00.0
140-145	1	3.3	0	00.0
146 – 150	0	00.0	1	03.3
151 -155	5	16.7	14	46.7
>155	24	80.0	15	50.0
WEIGHT				
<51	0	00.0	0	00.0
51-55	2	6.7	2	6.7
56-60	16	53.3	15	50.0
>60	12	40.0	13	43.3

Temperature				
96-97	0	.0	0	.0
98-99 F	23	76.7	23	76.7
99-100 F	7	23.3	7	23.3
>100F	0	.0	0	.0
SBP				
<101	0	.0	0	.0
101-110 mm hg	2	6.7	2	6.7
111-120 mm hg	10	33.3	13	43.3
121-130 mm hg	15	50.0	11	36.7
>130	3	10.0	4	13.3
DBP				
<61	0	.0	0	.0
61-70 mm hg	7	23.3	9	30.0
70-80 mm hg	14	46.7	12	40.0
>80 mm hg	9	30.0	9	30.0

Table 2 illustrates that most of patients were non vegetarians (66.7%, 63.3%) , non smokers and non alcoholics (40.0%, 40.0%), used analgesics for pain relief (53.3%,53.3%) and had temperature between 98-99f (76.7%, 76.7) in both control and experimental group respectively. Majority of the patients' height was >155cm (80%,50%), nearly half of the patients' weight was 56-60kg (53.3%, 50.0%), with systolic blood pressure of 121-130 mm hg (50%) in control group and 111- 120mm hg (43.3%) in experimental group and diastolic blood pressure of 70-80 mm hg (46.7%40%) in both control an experimental group respectively.

Fig: 4 suggests that nearly half of the patients had urinary disease (43.30%, 50%), in control and experimental group respectively.

Fig.5 shows that most of the patients had no history of cardiovascular disease (63.30%, 56.70%) or diabetic mellitus (63.30%, 60%) and around half of the patients had hypertension (53.30%, 46.70%) in control and experimental group respectively.

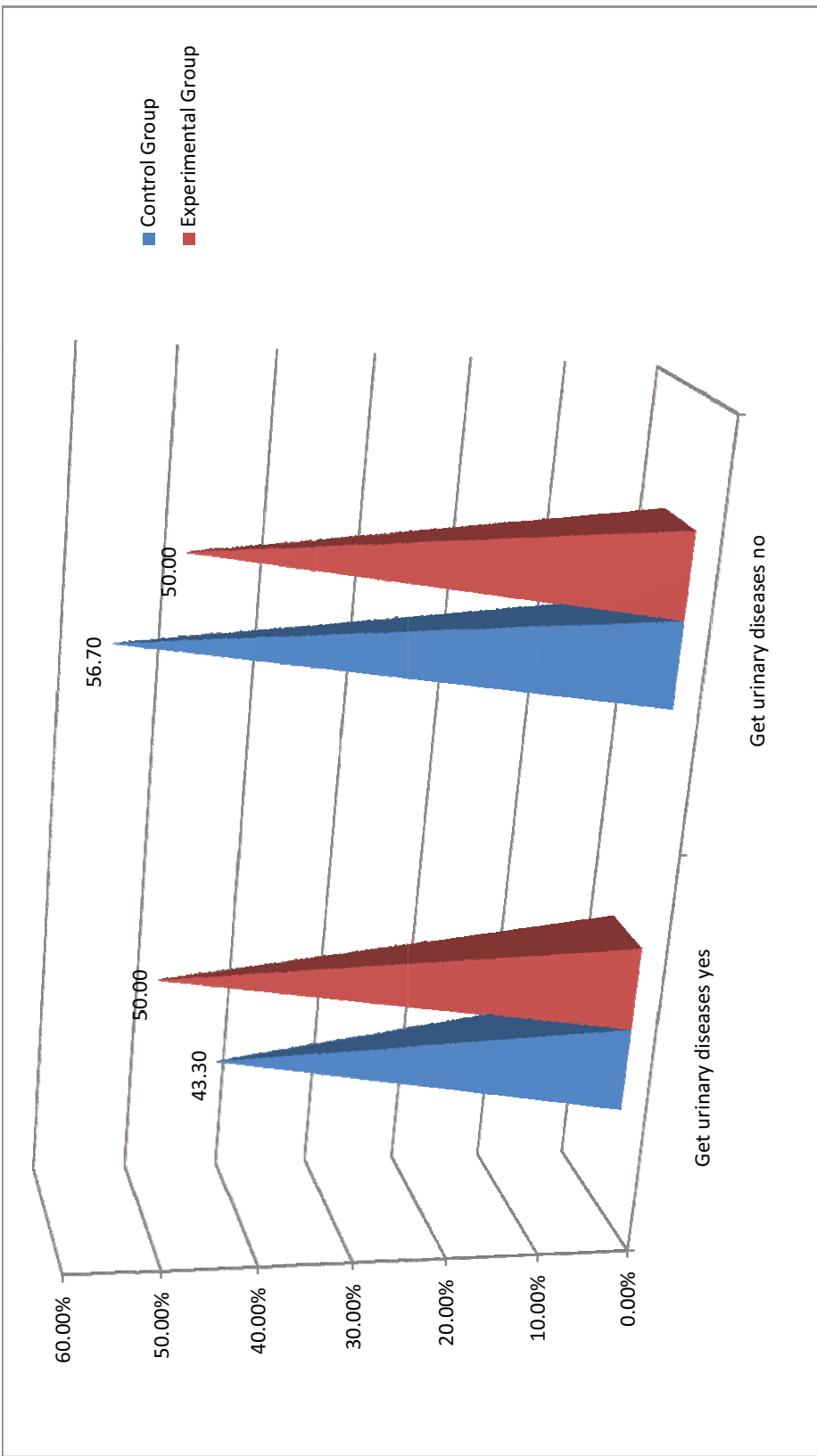


Fig.6. Percentage Distribution of urinary diseases among control and experimental group of patients undergoing hemodialysis.

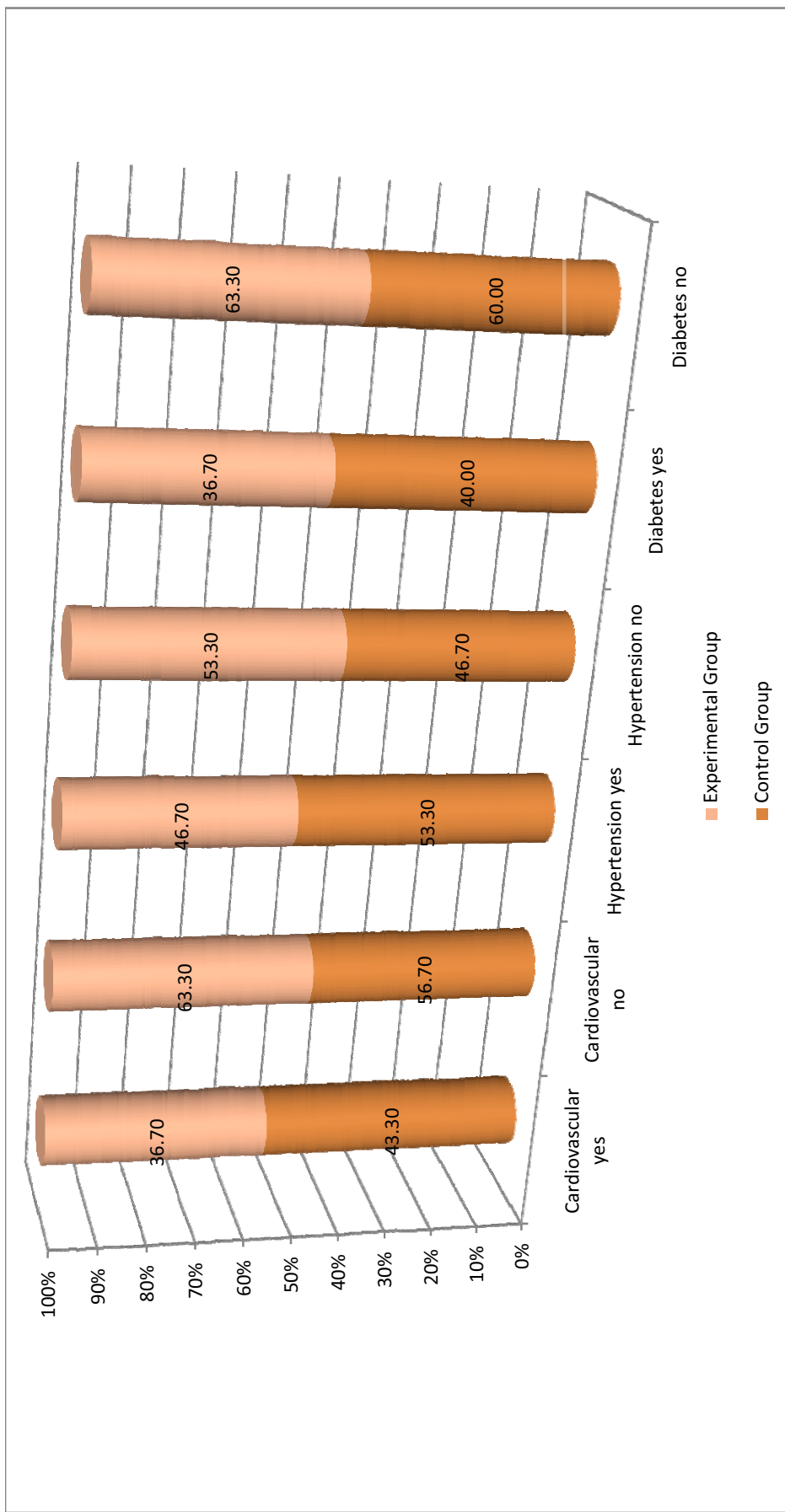


Fig.7. Percentage Distribution of History of cardiovascular disease , hypertension and diabetes among control experimental group patients undergoing hemodialysis.

Table. 3

Frequency and Percentage Distribution of Level of muscle cramps in the Control and Experimental Group of Patients Undergoing Hemodialysis.

Level of pain	Control Group (n=30)					Experimental Group (n=30)				
	Pre test			Post test		Pre test		Post test		
		f	%	f	%	f	%	f	%	
None		-	-	-	-	-	-	12	40	
Mild		-	-	-	-	-	-	18	60	
Moderate		16	53	11	36.67	17	57	-	-	
Severe		14	47	19	63.33	13	43	-	-	

From table 3 it is noted that most of the patients undergoing hemodialysis had moderate level of muscle cramps (53%,57%) in pre test among control and experimental group respectively, whereas in post test most the patients had severe level of muscle cramps (63.33%) in control group and only mild level of muscle cramps (60%) in experimental group.

Table.4

Comparison of Mean and Standard Deviation of Level of muscle cramp between Control and Experimental Group of patients Undergoing Hemodialysis in pre test and post test.

Group	Control group (n =30)		Experimental group (n =30)		t value
	M	SD	M	SD	
Pre Test	6.73	1.28	6.60	1.27	-.403
Post Test	6.87	1.20	5.8	0.65	4.86***

***P< 0.001

Data from table 4 indicates that, the pretest the mean scores and standard deviation of muscle cramps is (M=6.73,SD =1.28)in control group and (m=6.6, SD=1.27) in experimental group with t' value -.403 whereas the post test mean scores and standard deviation of muscle cramps is (M= 6.87, SD= 1.20) in control group and(M= 5.8, SD= 0.65) in experimental group with t' value of 4.86 at P< 0.001 level. Hence the null hypothesis Ho1 “There will be no significant difference in the pretest and post test scores of muscle cramps between control and experimental group of clients undergoing hemodialysis” was rejected.

Table.5

Frequency and Percentage Distribution of Level of Satisfaction Scores of Intradialytic Stretching Exercises in the Experimental Group of patients Undergoing Hemodialysis.

(n=30)

Domain	Highly Satisfied		Moderate satisfied		just satisfied		dis satisfied	
	n	p	n	p	n	P	n	P
About the method of Exercise	28	93.33	2	6.67	-	-	-	-
About the effect of the Exercise	27	90.00	3	10.00	-	-	-	-
About the researcher	28	93.33	2	6.67	-	-	-	-

It can be inferred from table 5 that majority of the patients undergoing hemodialysis in experimental group were highly satisfied with the method application of intradialytic stretching exercise (93.33%), the effectiveness of therapy (90%) and approach of researcher (93.33%).

Table. 6

Association between the Selected Demographic Variables and the Level of muscle cramps among the Control and Experimental Group of patients Undergoing Hemodialysis.

Demographic Variable	Experimental Group			Control Group		
	(n=30)			(n=30)		
	Post test			Post test		
	Above mean	Below mean	χ^2	Above mean	Below mean	χ^2
Age						
less than 30 years	6	1	2.57	2	2	1.80
More than 30 years	12	11	df=1	17	9	df=1
Gender						
Male	8	10	3.53	13	6	0.57
Female	10	2	df=1	6	5	df=1
Education						
No formal education	2	3	1.00	0	0	2.67
Educated	16	9	df=1	19	11	df=1
Occupation						
Unemployed	2	3	1.00	1	2	1.29
Employed	16	9	df=1	18	9	df=1
Nature of work						
Sedentary& moderate	10	8	0.37	15	11	2.67
Heavy	8	4	df=1	4	0	df=1

It can be inferred from table 6 that there was no significant association between selected demographic variables namely age, gender, educational status, occupation, nature of work and level of muscle cramp in control and experimental group of patients. Hence the null hypothesis H_0 “There will be no significant association between selected demographic variables- age, gender, educational status, occupation, nature of work and the level of muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.

Table. 7

Association between the Selected Clinical Variables and the Level of muscle cramps among Control and Experimental Group of patients undergoing Hemodialysis.

Clinical Variables	Experimental Group (n=30)			Control Group (n=30)		
	Post test			Post test		
	Above mean	Below mean	χ^2	Above mean	Below mean	χ^2
Height						
< 155	2	4	2.22	10	5	0.13
>155	16	8	df=1	9	6	df=1
Weight						
<60	12	6	0.83	9	8	1.83
>60	6	6	df=1	10	3	df=1
Temperature						
98-99 f	12	11	2.51	13	10	1.96
>99	6	1	df=1	6	1	df=1
SBP						
<120	8	4	0.37	10	5	0.14
>120 mm hg	10	8	df=1	9	6	df=1
DBP						
<80	12	9	0.23	14	7	0.33
>80 mm hg	6	3	df=1	5	4	df=1
Medication						
Antibiotics & others	8	6	0.08	9	5	0.01
Analgesics	10	6	df=1	10	6	df=1
History of Smoking and Alcoholism						
Smoking/alcoholism	8	10	4.53	10	8	0.08
No	10	2	df=1	6	6	df=1

Type of Diet						
Vegetarian	7	3	0.62	7	4	0.00
Non vegetarian	11	9	df=1	12	7	df=1
History of Urinary Diseases						
Yes	8	5	0.02	7	8	3.58
No	10	7	df=1	12	3	df=1
History of Cardiovascular Diseases						
Yes	10	3	2.73	8	3	0.66
No	8	9	df=1	11	8	df=1
History of Hypertension						
Yes	9	7	0.20	7	7	2.01
No	9	5	df=1	12	4	df=1
History of Diabetes						
Yes	6	6	0.83	5	6	2.39
No	12	6	df=1	14	5	df=1

It can be depicted from the table 6 that there was no significant association between selected clinical variables like blood pressure, temperature and level of pain in control and experimental group of patients. Hence the null hypothesis H_0 3 “There will be no significant association between selected clinical variables- blood pressure, temperature and level of muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.

Summary

This chapter has dealt with the analysis and interpretation of the data obtained by the researcher. The analysis of the results showed that the level of muscle cramps was decreased after intradialytic stretching exercises when compared to the level of muscle cramps before intradialytic stretching exercises. This can be credited to the effectiveness of intradialytic stretching exercises.

Chapter V

Discussion

CHAPTER V

DISCUSSION

An Experimental Study to Assess the Effect of Intradialytic Stretching Exercises on Muscle Cramps Among Patients Undergoing Hemodialysis in Selected Apollo Hospitals at Chennai.

Objectives of the Study

1. To assess the level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
2. To determine the effectiveness of intradialytic stretching exercise on muscle cramp comparing the level of muscle cramps between control group and experimental group of patients undergoing hemodialysis.
3. To assess the level of satisfaction of patients regarding intradialytic stretching exercises on muscle cramps among experimental group of patients undergoing hemodialysis.
4. To find out the association between the selected demographic variables and level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
5. To find out the association between the selected clinical variables and level of muscle cramps among control and experimental group patients undergoing hemodialysis.

The discussion is presented under the following headings

The findings of the study was organized and presented under the following headings.

- Frequency and percentage distribution of selected demographic variables of the control and experimental group of patients undergoing hemodialysis
- Frequency and percentage distribution of clinical variables of the control and experimental group patients undergoing hemodialysis.
- Frequency and Percentage Distribution of Level Muscle cramps Perception among After intradialytic stretching exercises in the Control and Experimental Group of patients Undergoing Hemodialysis.
- Comparison of mean and standard deviation of level of muscle cramps between control and experimental group of patients undergoing hemodialysis.
- Frequency and percentage distribution of level of satisfaction scores of intradialytic stretching exercises among the experimental group of patients undergoing hemodialysis.
- Association between the selected demographic variables and the level of muscle cramps among the control and experimental group of patients undergoing hemodialysis
- Association between the selected clinical variables and the level muscle cramps among control and experimental group of patients undergoing hemodialysis.

Demographic Variables in the Control and Experimental Group of Patients Undergoing Hemodialysis

In this study significant percentage of the patients undergoing hemodialysis were in the age group of 31-35years (33.30%) and >35 years (46.70%), qualified up to higher secondary education (23.3,43.3%) and majority were married (73.3%, 90.0%) in control and experimental group respectively. Most of the patients were male (60.00%, 63.30%), moderate workers (40%,56.6%) with an annual income of <3 lakhs (40.0%), and 3-5 lakhs(43.3%) in control group and experimental group respectively.

Age is one of the critical factors affecting a person's physical and psychological state of health. This shows that the incidence of lifestyle disorders especially chronic kidney disorders increases with increasing age. Also, pain tolerance and threshold reduces and severity of pain gradually increases with aging. This reduced tolerance to pain may be due to age related deterioration of nervous system which senses pain much more and elicits an increased response to pain. The response may also depend upon the frequency, duration and the severity of pain.

This is consistent with the study conducted on Nurcan (2011) to measure the level of pain associated with aging by using intradialytic stretching exercises. It was found that there was a reduction in the level of pain with intradialytic stretching exercises. Similar findings were obtained by the investigator in the present study.

Clinical Variables in the Control and Experimental Group of Patients Undergoing Hemodialysis

In the present study most of patients were non vegetarians (66.7%, 63.3%), non smokers and non alcoholics (40.0%, 40.0%), used analgesics for pain relief (53.3%,53.3%) and had temperature between 98-99f (76.7%, 76.7) in both control and experimental group of patients respectively. Majority of the patients' height was >155cm (80%,50%), nearly half of the patients' weight was 56-60kg (53.3%, 50.0%), with systolic blood pressure of 121-130 mm hg (50%) in control group and 111- 120mm hg (43.3%) in experimental group and diastolic blood pressure of 70-80 mm hg (46.7%40%) in both control an experimental group respectively.

Nearly half of the patients had urinary disease (43.30%, 50%), hypertension (53.30%, 46.70%) and most of the patients had no history of cardiovascular disease (63.30%, 56.70%) or diabetic mellitus (63.30%, 60%) in control and experimental group respectively.

Corbett(1971) conducted a study to evaluate the effect of spontaneous and induced muscle spasms on blood pressure, heart rate, hand blood flow, calf blood flow and occluded vein pressure in the hand and foot in non-bedridden patients with chronic, closed, complete, localized transection of the cervical spinal cord. Both types of spasm produced a similar response consisting of an increase in blood pressure and occluded vein pressure and a decrease in heart rate and hand and calf blood flow. The changes commenced within 2-3 sec and usually reached maxima in 20-30 sec. On some occasions there was a temporary initial increase in heart rate and calf blood flow. The changes occurred independently of changes in bladder pressure. It is concluded that the changes in peripheral blood vessels result from a spinal sympathetic reflex to somatic afferents associated with muscular contraction. Similarly association was expected by the investigator between predetermined clinical variables and level of muscle cramps in the study.

Level of Pain Perception During Muscle Cramps Among the Control and Experimental Group of Patients Undergoing Hemodialysis.

It is noted that most of the patients undergoing hemodialysis had moderate level of muscle cramps (53%,57%) in pre test among control and experimental group respectively, whereas in post test most the patients had severe level of muscle cramps (63.33%) in control group and only mild level of muscle cramps (60%) in experimental group.

Thus the present study concludes that pain intensity and severity can be altered with intradialytic stretching exercises at the site of muscle cramps to relieve the irritation associated with the severity of pain during hemodialysis by numbing the site or area of muscle cramps.

This is inconsistent with the study conducted by Demir et al (2010) to evaluate the effectiveness of use of intradialytic stretching exercises for control of pain associated with muscle cramps and its results proved that there is a significant reduction in the level of pain associated with muscle cramps.

Comparison of Mean and Standard Deviation of level Muscle Cramps between Control and Experimental Group of Patients Undergoing Hemodialysis.

It is noted that pretest mean scores and standard deviation of muscle cramps is (M=6.13,SD =1.28)in control group and (m=6.6, SD=1.27) in experimental group with t' value -.403 whereas the post test mean scores and standard deviation of muscle cramps is (M= 6.87, SD= 1.20) in control group and(M= 5.8, SD= 0.65) in experimental group with t' value of 4.86 at $P < 0.001$ level. Hence the null hypothesis H_0 1 “There will be no significant difference in the pretest and post test scores of muscle cramps between control and experimental group of clients undergoing hemodialysis” was rejected.

The investigator's finding were consistent with the study conducted by Leyla et al (2012) who investigated the effect of intradialytic stretching exercises on pain undergoing hemodialysis. The study results showed that intradialytic stretching exercises reduced the intensity of pain due to muscle cramps.

This shows that intradialytic stretching exercises is effective in minimizing pain during hemodialysis. By incorporating intradialytic stretching exercises in muscle cramps protocol can help nurses to achieve patients satisfaction and

comfort by reducing the level of pain without any adverse effects as this acts as a physical analgesia.

Level of Satisfaction Scores of Intradialytic Stretching Exercises in the Experimental Group of Patients Undergoing Hemodialysis.

Majority of the patients undergoing hemodialysis in experimental group were highly satisfied with the method application of intradialytic stretching exercise (93.33%), the effectiveness of therapy (90%) and approach of researcher (93.33%).

The health care system is basically a service based industry and patients satisfaction is very much important to obtain a positive outcome. Nursing care is a key determinant to obtain a healthier positive outcome and also to acquire overall patients satisfaction. If hospital nursing services has to provide the highest possible quality nursing care in terms of total patients needs, then the basic nursing care has to be strengthened.

Thus intradialytic stretching exercise as basic nursing skills helps to reduce muscle cramp, cost effective increases patients satisfaction, enhances nurse client relationship and thus provides nurses a better job satisfaction with regard to implementation of best available nursing skills to minimize muscle cramp without adverse effects.

The findings of this study is supported by Takhreem et al (2008) in a study to assess a causal relationship between exercise intervention of CKD patients. Exercising patients have shown improvements in physical fitness,

psychological function, manual dexterity, reaction times, and lower-extremity muscle strength. All of these factors help improve health status and satisfaction.

Association Between the Selected Demographic Variables and the level Muscle Cramps Among Control and Experimental Group of Patients Undergoing Hemodialysis.

There was no significant association between selected demographic variables namely age, gender, educational status, occupation, nature of work and level of pain in control and experimental group of clients. Hence the null hypothesis H_0 2 “There will be no significant association between selected demographic variable and pre -test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.

The investigator findings were supported by the study conducted by Nurcan et al (2011) to study the effect of intradialytic stretching exercise on pain. The study thus concluded that there was a significant difference on pain with intradialytic stretching exercise prior to and after the intervention. The study also indicated that age, gender, education has no effect on muscle cramps.

This shows that everybody elicit quite a brisk response to pain and irritation with muscle cramps. Demographic characteristics have got no role to play with presence of pain and its intensity. Thus intradialytic stretching exercise can be used to reduce the level of muscle cramps regardless of age, sex, and other demographic variables.

Association Between the Selected Clinical Variables and the Level of Muscle Cramps Among Control and Experimental Group of Patients Undergoing Hemodialysis.

There was no significant association between selected clinical variables like weight, height, systolic BP, diastolic BP, history of smoking and alcoholism, type of diet, urinary diseases, history of cardiovascular diseases, history of hypertension, history of diabetes etc and level of pain in control and experimental group of clients. Hence the null hypothesis H_03 “There will be no significant association between selected clinical variable and pre-test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.

Ridley, et al.,(1999)conducted a quasi experimental one group pre and post test design study. Eight subjects completed a 12 week exercise programme involving warm-up, stretching, strengthening and cardio vascular training. The result demonstrated improvements in participants, physical capacity, quality of life and ability to perform activities of daily living.

This study helps to concluded that an exercise during dialysis, programme was safe and had the potential to result in positive patient outcomes. Exercises provided during hemodialysis do not cost patients extra time and will be effective in decreasing the level of fatigue and increasing potential for performing their daily activities. Providing these exercises with dialysis will improve the effectiveness of dialysis and alleviates long term complications of the same. So intradialytic stretching exercise can be incorporated in muscle cramps protocol and used in general for all clients with hemodialysis.

Summary

This chapter dealt with the discussion of findings in the present study which includes demographic variables of patients, clinical variables of patients, level of patients satisfaction, and level of pain of patients with intradialytic stretching exercise during hemodialysis.

Chapter VI

Summary, Conclusion, Implications

Recommendations

CHAPTER VI

SUMMARY, CONCLUSION, IMPLICATION AND RECOMMENDATION

This is the most creative and demanding part of the study. This chapter gives a brief account of the present study including the conclusion drawn from the finding, recommendations, limitations of the study, suggestions for the study and nursing implications.

Summary

The present study was indented to analyze the Effectiveness of Intradialytic Stretching Exercise and the Level of muscle cramps in patients with Muscle Cramps Undergoing Hemodialysis at Apollo Hospitals Chennai.

Objectives of the Study

1. To assess the level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
2. To determine the effectiveness of intradialytic stretching exercise on muscle cramp comparing the level of muscle cramps between control group and experimental group of patients undergoing hemodialysis.
3. To assess the level of satisfaction of patients regarding intradialytic stretching exercises on muscle cramps among experimental group of patients undergoing hemodialysis.
4. To find out the association between the selected demographic variables and level of muscle cramps among control and experimental group of patients undergoing hemodialysis.
5. To find out the association between the selected clinical variables and level of muscle cramps among control and experimental group patients undergoing hemodialysis.

Null Hypotheses

- Ho1:** There will be no significant difference between pretest and post test scores of muscle cramps in control and experimental group of patients undergoing hemodialysis.
- Ho2:** There will be no significant association between selected demographic variables and pre -test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis.
- Ho3:** There will be no significant association between selected clinical variables and pre-test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis.

The conceptual framework for the study was developed on the basis of King's Goal Attainment Model, which was modified for the present study. An intensive review of literature and experts guidance laid the foundation to the development of tools such as demographic variables proforma, clinical variables proforma, and patient satisfaction rating scale.

In this study, true experimental research design was adopted. The present study was conducted at Apollo hospitals, Chennai intradialytic stretching exercises for muscle cramps among patients undergoing hemodialysis. The sample size for the present study was 60 patients with muscle cramps, among which, 30 patients were assigned to control group and 30 clients to experimental group who satisfied the inclusion criteria. The investigator used the demographic and clinical variables proforma of patients to obtain the baseline data. Standardized Numerical rating pain assessment intradialytic stretching exercises for muscle cramps and rating scale to assess the level of satisfaction of patients

about intradialytic stretching exercises for muscle cramps. The data collection tools were validated and reliability was established. After the pilot study, the data collection of main study was conducted for period of 4 weeks. The collected information was tabulated and analyzed by using appropriate descriptive and inferential statistics.

The Major Findings of the Study

Demographic Variables of the Control and Experimental Group of Patients Undergoing Hemodialysis.

A significant percentage of the patients undergoing hemodialysis were in the age group of 31-35 years (33.30%) and >35 years (46.70%), qualified up to higher secondary education (23.3, 43.3%) and majority were married (73.3%, 90.0%) in control and experimental group respectively. Most of the patients were male (60.00%, 63.30%), moderate workers (40%, 56.6%) with an annual income of <3 lakhs (40.0%), and 3-5 lakhs (43.3%) in control group and experimental group respectively.

Clinical Variables of the Control and Experimental Group of Patients Undergoing Hemodialysis.

Most of patients were non vegetarians (66.7%, 63.3%), non smokers and non alcoholics (40.0%, 40.0%), used analgesics for pain relief (53.3%, 53.3%) and had temperature between 98-99f (76.7%, 76.7) in both control and experimental group of patients respectively. Majority of the patients' height was >155cm (80%, 50%), nearly half of the patients' weight was 56-60kg (53.3%, 50.0%), with systolic blood pressure of 121-130 mm hg (50%) in control group and

111- 120mm hg (43.3%) in experimental group and diastolic blood pressure of 70-80 mm hg (46.7%40%) in both control an experimental group respectively.

Nearly half of the patients had urinary disease (43.30%, 50%), hypertension (53.30%, 46.70%) and most of the patients had no history of cardiovascular disease (63.30%, 56.70%) or diabetic mellitus (63.30%, 60%) in control and experimental group respectively.

Level of Pain Perception During Muscle Cramps Among the Control and Experimental Group of Patients Undergoing Hemodialysis.

Most of the patients undergoing hemodialysis had moderate level of muscle cramps (53%,57%) in pre test among control and experimental group respectively, whereas in post test most the patients had severe level of muscle cramps (63.33%) in control group and only mild level of muscle cramps (60%) in experimental group.

Comparison of Mean and Standard Deviation of Level Muscle Cramps Between Control and Experimental Group of Patients Undergoing Hemodialysis.

The pretest mean scores and standard deviation of muscle cramps is (M=6.13,SD =1.28)in control group and (m=6.6, SD=1.27) in experimental group with t' value -.403 whereas the post test mean scores and standard deviation of muscle cramps is (M= 6.87, SD= 1.20) in control group and(M= 5.8, SD= 0.65) in experimental group with t' value of 4.86 at $P < 0.001$ level. Hence the null hypothesis Ho1 “There will be no significant difference in the pretest and post test scores of muscle cramps between control and experimental group of clients undergoing hemodialysis” was rejected.

Level of Satisfaction Scores of Intradialytic Stretching Exercises in the Experimental Group of Patients Undergoing Hemodialysis.

Majority of the patients undergoing hemodialysis in experimental group were highly satisfied with the method application of intradialytic stretching exercise (93.33%), the effectiveness of therapy (90%) and approach of researcher (93.33%).

Association Between the Selected Demographic Variables and the Level of Muscle Cramps Among the Control and Experimental Group of Patients Undergoing Hemodialysis.

There was no significant association between selected demographic variables namely age, gender, educational status, occupation, marital status, nature of work and level of muscle cramps in control and experimental group of patients. Hence the null hypothesis H_02 “There will be no significant association between selected demographic variable and pre -test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.

Association Between the Selected Clinical Variables and the Level of Muscle Cramps Among the Control and Experimental Group of Patients Undergoing Hemodialysis.

There was no significant association between selected clinical variables like weight, height, systolic BP, diastolic BP, history of smoking and alcoholism, type of diet, history of urinary diseases, history of cardiovascular diseases, history of hypertension, history of diabetes etc and level of muscle cramps in control and

experimental group of patients. Hence the null hypothesis H_0 3 “There will be no significant association between selected clinical variable and pre-test level of muscle cramps among the control and experimental group of patients undergoing hemodialysis” was retained.

Conclusion

Intradialytic stretching exercise is proposed as a means of relieving muscle cramps in a timely and cost effective manner. The findings of the study indicated that it will relieve muscle cramps and improve the patients level of satisfaction and comfort in regard undergoing hemodialysis.

Implications

The findings of the study has implications in the different branches of nursing profession i.e. nursing practice, nursing education, nursing administration and nursing research.

Nursing Practice

Nurses have a major role in assessing and providing muscle cramps relief. All the clinical nurses should attend short term courses and update their knowledge regarding pain assessment and pharmacological and non pharmacological management of pain which would thereby help in providing quality and efficient care to the clients.

Nursing Theory

The conceptual and theoretical models exclusively for pain relief yet to be developed by nursing theorists. The clinical framework of the present study is

based on king's goal attainment model. This model provide framework to identify needs of the client in an organized manner and it can be used to intervene the clients appropriately and evaluate the client outcome and satisfaction

Nursing Education

The emerging health care trends of nursing education must focus on non pharmacological nursing methods of pain management which will help to enhance nursing Our nursing students should be made aware of different methods of relieving and managing pain, as it greatly influences the clients' outcome. Nurse educators should take initiatives to publish articles in journals related to pain management during hemodialysis.

Nursing Administration

The nurse administrators have responsibility to provide nurses with substantive continuing education opportunities. This will enable the nurses to update their knowledge, acquire special and demonstrate high quality care.

Nursing administrators should take the initiative in organizing educational programs on pain management for the nursing personnel in the hospital to gain adequate knowledge. Nurse administrators should also conduct periodical review meetings to evaluate the quality of pain management.

Nursing administrator should collaborate with governing bodies in formulating policies and protocols for pain management to emphasize nursing care and plan for material, methods and time to conduct successful and useful education programs of pain reduction strategies.

Nursing Research Nursing

There is a need for extensive and intensive research in this area. It opens a big avenue for research on comparison of pharmacological and non pharmacological methods of pain relief and comparison can also be made between different non pharmacological methods to relieve pain. Dissemination of the findings of the research.

Through conferences, seminars, publications in national and international nursing journals will benefit a wider community.

Recommendations

- A similar study could be undertaken on larger scale for more valid generalization.
- This study could be replicated in different settings.
- The study could be conducted to compare different non pharmacological methods of pain management.
- Pain management protocol with incorporated intradialytic stretching exercises application can be made and put in to practice.

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Appendices

APPENDIX I

LETTER SEEKING PERMISSION TO CONDUCT THE STUDY



Apollo College of Nursing

(Recognised by the Indian Nursing Council and Affiliated to the Tamil Nadu Dr. M.G.R. Medical University, Chennai)

CO/0279/14

25.06.2014

To

Dr.C.Paul Dilip Kumar
Asst. Director Medical services
Apollo Specialty Hospital
Vanagaram
Chennai – 600 095.

Respected Sir,

Sub.: To request permission for research study – Reg.

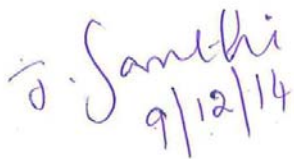
Greetings! As part of the curriculum requirement our 2nd year M.Sc. (N) student Ms.Priya Krishna has selected the following title for her research study.

“An experimental Study to Assess the Effect of Intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis in selected Apollo Hospitals at Chennai.”

So I kindly request your goodselves to permit her to conduct study in your esteemed hospital.

Thanking you,


Dr. LATHA VENKATESAN
PRINCIPAL


Dr. Santhi
9/12/14


IS/ISO 9001:2000



Vanagaram to Ambattur Main Road, Ayanambakkam, Chennai - 600 095.
Ph. : 044 - 2653 4387 Tele fax : 044 - 2653 4923 / 044- 2653 4386



Apollo College of Nursing

(Recognised by the Indian Nursing Council and Affiliated to the Tamil Nadu Dr. M.G.R. Medical University, Chennai)

CO/0279/14

25.06.2014

To

Dr. Radha Rajagopalan
Director of Medical Education
Apollo Main Hospitals
Greaves Road
Chennai- 600 006.

Respected Madam,

Sub.: To request permission for research study – Reg.

Greetings! As part of the curriculum requirement our 2nd year M.Sc. (N) student Ms. Priya Krishna has selected the following title for her research study.

“An experimental Study to Assess the Effect of Intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis in selected Apollo Hospitals at Chennai.”

So I kindly request your good selves to permit her to conduct study in your esteemed hospital.

Thanking you,

Dr. LATHA VENKATESAN
PRINCIPAL

Let to Dr. Subba Rao
Ms. Purnima for helping this condition
Aditi
Poobhakam
Please help them
Deepa (BB Subbarao)

IS/ISO 9001:2000



Vanagaram to Ambattur Main Road, Ayanambakkam, Chennai - 600 095.
Ph. : 044 - 2653 4387 Tele fax : 044 - 2653 4923 / 044- 2653 4386

APPENDIX II

ETHICS COMMITTEE CERTIFICATE

Ethics Committee



29 October, 2014

To,
Mrs. PriyaKrishna,
Msc Nursing,
Apollo College of Nursing, Chennai.

Ref: An experimental study to assess the effect of intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis in selected Apollo Hospitals at Chennai.

Sub: Approval of the above referenced project and its related documents.

Dear Mrs. Priykrishna,

Ethics Committee-Apollo Hospitals has received the following document submitted by you related to the conduct of the above-referenced study.

- Project Proposal
- Informed Consent Form

The Ethics Committee-Apollo Hospitals reviewed and discussed the Project proposal documents submitted by you related to the conduct of the above referenced Project at its meeting held on 28 October, 2014.

The following Ethics Committee Members were present at the meeting held on 28 October, 2014.

Name	Gender	Designation	Affiliation	Position in the committee
Dr. P. Nalini Rao	F	Independent Consultant	Independent Consultant, Chennai	Chairperson (Social Scientist)
Dr. Rema Menon	F	Blood Bank Officer	Apollo Hospitals, Chennai	Member Secretary
Dr. P.Muralidaran	M	Pharmacologist	CLBMCP, Chennai	EC-Member (Pharmacologist)
Mrs. S.V. Mathanghi	F	Executive- project	Apollo Pharmacy, Chennai	EC-Member (Layperson)
Dr. K. Sathyamurthi	M	Asst. Professor	Madras School of Social work, Chennai	EC-Member (Social Scientist)
Dr. VijayaKumar Chockan	M	Medical Superintendant	Apollo Speciality Hospitals, Chennai	EC-Member (Clinician)

Apollo Hospitals Enterprise Limited
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Ethics Committee

Dr. Harikrishna Reddy	M	Consultant physician	Apollo Hospitals, Chennai	EC-Member (Clinician)
Mr. Philip.T.Paul	M	Lawyer	Independent Legal Practitioner	EC-Member (Lawyer)

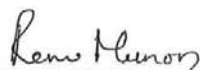
After due ethical and scientific consideration, the Ethics Committee has approved the above presentation submitted by you.

The EC review and approval of the report is only to meet the academic requirement and will not amount to any approval of the conclusions / recommendations as conclusive, deserving adoption and implementation, in any form, in any healthcare institution.

The Ethics Committee is constituted and works as per ICH-GCP, ICMR and revised Schedule Y guidelines.

With Regards,

Date: 29/10/14.



Dr. Rema Menon,
Ethics Committee-Member Secretary,
Apollo Hospitals, Chennai,
Tamil Nadu, India.

Dr. REMA MENON
MEMBER SECRETARY
ETHICS COMMITTEE, APOLLO HOSPITALS
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APPENDIX III
LETTER SEEKING PERMISSION FOR CONTENT VALIDITY

From

Ms.priyakrishna.
M.Sc. (Nursing) Second Year,
Apollo College of Nursing,
Chennai – 600 095.

To

Forwarded Through:
Dr. LathaVenkatesan,
Principal,
Apollo College of Nursing.

Sub: Requesting for opinions and suggestions of experts for establishing content validity for research tool.

Respected Madam,

I am a postgraduate student of the Apollo College of Nursing. I have selected the below mentioned topic for research project to be submitted to The Tamil Nadu Dr. M.G.R Medical University, Chennai as a partial fulfillment of Masters of Nursing Degree. **“An experimental study to assess the effect of intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis in selected apollo hospitals at chennai.”** With regards may I kindly request you to validate my tool for its appropriateness and relevancy. I am enclosing the Background, Need for the study, Statement of the problem, Objectives of the study, Demographic Variable Proforma, Clinical Variable Proforma, Observation Schedule on Pulmonary Parameters and Satisfaction Rating Scale for clients with intradialytic stretching exercises. I would be highly obliged and remain thankful for your great help if you could validate and send it as soon as possible.

Thanking you,

Date:

Yours sincerely,

Place:

Ms priyakrishna

APPENDIX IV
LIST OF EXPERTS

- 1. Dr. LathaVenkatesan, M.Sc (N), M.Phil. (N)., Ph.D.(N),**
Principal and Professor in Maternity Nursing,
Apollo College of Nursing,
Chennai- 600 095

- 2. Prof. Lizy Sonia. A, M.Sc.(N),**
Vice Principal and Professor in Medical Surgical Nursing,
Apollo College of Nursing,
Chennai-600 095

- 3. Dr. P. Visweswar Reddy., M.D,**
Internal Medicine, D.M., (Nephrology), F.C.C.P,
F.S.A.S. M.S,
Apollo specialty Hospital
Vanagaram,
Chennai – 600 095.

- 4. Prof. K. Vijayalakshmi, M.Sc.(N),**
Professor in Psychiatric Nursing,
Apollo College of Nursing,
Chennai- 600 095

- 5. Mrs. NesaSathyaSatchi, M.Sc.(N),**
Professor in Pediatric Nursing,
Apollo College of Nursing,
Chennai- 600 095

- 6. Mrs. JaslinaGnanarani .J, M.Sc.(N),**
Reader in Medical Surgical Nursing,
Apollo College of Nursing,
Chennai- 600 095

- 7. Mrs. D.Sasi Kala, M.Sc.(N),**
Reader in Medical Surgical Nursing
Apollo College Of Nursing
Chennai-600 095
- 8. Mrs. G.Kanchana, M.Sc. (N),**
Reader in Medical Surgical Nursing,
Apollo College of Nursing,
Chennai-600 095
- 9. Mrs.P. Kasthuri, M.Sc. (N),**
Lecturer in Medical Surgical Nursing,
Apollo College of Nursing,
Chennai- 600 095

APPENDIX V
CERTIFICATE FOR CONTENT VALIDITY

TO WHOMSOEVER IT MAY CONCERN

This is to certify that tools and content for the research study developed by II year M.Sc (Nursing) student of Apollo College of Nursing for her dissertation “An experimental study to assess the effect of intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis in selected apollo hospitals at chennai” was validated.

Signature of the Expert

Name and Designation

APPENDIX VI
LETTER SEEKING CONSENT FROM PARTICIPANTS

Dear participant/ bystander,

I am priyakrishna M.Sc. Nursing student of Apollo College of Nursing, Chennai. As a part of my study, a research on “An experimental study to assess the effect of intradialytic stretching exercises on muscle cramps among patients undergoing hemodialysis in selected apollo hospitals at chennai”

I hereby seek your consent and co-operation to participate in the study. Please be frank and honest in response. The information obtained will be kept confidential and anonymity will be maintained.

Signature of the researcher

IHereby consent to participate my relative in this study


Place:

Date:

Signature of the participant/ bystander

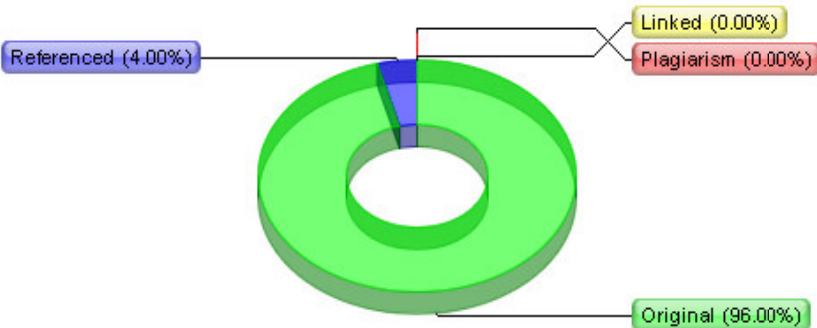
APPENDIX VII
CERTIFICATE FOR ENGLISH EDITING

This is to certify that the desertation entitled **“An Experimental Study to assess the effect of Intradialytic Stretching Exercises on Muscle Cramps among Patients Undergoing Hemodialysis in Selected Apollo Hospitals at Chennai”** by Priya Krishna II year M.Sc student Apollo College of Nursing, was edited for English Language appropriateness.


T. R. RAJASREE, M.A., B.Ed
Head of the Department of English
CHAPOVAN JUNIOR COLLEGE,
MANAKALA, ADOR

APPENDIX VIII

PLAGIARISM ORIGINALITY REPORT

Plagiarism Detector - Originality Report	
Plagiarism Detector Project:[http://plagiarism-detector.com] Application core version:557	
Originality report details:	
Generation Time and Date:	04/10/2015 11:05:30 AM
Document Name:	PRIYA KRISHNA THESIS.doc
Document Location:	C:\Documents and Settings\Administrator\Desktop\ PRIYA KRISHNA THESIS. doc
Document Words Count:	16,627
Important Hint: To understand what exactly is meant by any report value - you can click, "Help image" . It will navigate you to the most detailed explanation at our web site.	
Plagiarism Detection Chart:	
	
Referenced 4% / Linked 0%	
Original - 96% / 0% - Plagiarism	

APPENDIX IX
DEMOGRAPHIC VARIABLE PROFORMA OF CLIENTS UNDERGOING
HEMODIALYSIS

Purpose

This proforma is used by the researcher to collect information on demographic variables such as age, gender, educational status, occupation, religion, marital status and monthly income.

Instructions

The researcher will collect the information by interviewing the participants and by referring the hospital records. Please be frank in your response. It will be kept confidential and anonymity will be maintained throughout the study.

Sample Number

1. Age in years

1.1 20 -25

1.2 26-30

1.3 31-35

1.4 ≥ 36

2. Gender

2.1 Male

2.2 Female

3. Educational status

3.1 No formal education

3.2 Primary School

3.3 High school

3.4 Higher secondary

3.5 College and above

4. Occupation

4.1 Student

4.2 Unemployed

4.3 Government

4.4 Private

4.5 Business

5. Nature of work

5.1 Sedentary

5.2 Moderate

5.3 Heavy

APPENDIX - X

CLINICAL VARIABLE PROFORMA

Purpose

This proforma is used by the researcher to collect information on Clinical variables such as height, weight, temperature, blood pressure and type of medication.

Instructions

The researcher will collect the information by interviewing the participants and by referring the hospital records. Please be frank in your response.

1. Height in cm

1.1 ≤ 135

1.2 136 -140

1.3 140-145

1.4 146 – 150

1.5 151 -155

1.6 ≥ 156

2. Weight in kg

2.1 ≤ 50

2.2 51-55

2.3 56-60

2.4 ≥ 60

3. Temperature

3.1 96° - 97° F

3.2 98° - 99° F

3.3 99° - 100° F

3.4 $\geq 101^{\circ}$ F

4. Systolic Blood pressure

4.1 ≤ 100 mm hg

4.2 101-110 mm hg

4.3 111-120 mm hg

4.4 121-130 mm hg

4.5 ≥ 131 mm hg

5. Diastolic blood pressure

5.1 ≤ 60 mm hg

5.2 61-70 mm hg

5.3 70-80 mm hg

5.4 ≥ 81 mm hg

6. Type of Medication

6.1 Antibiotics

6.2 Analgesics

6.3 Others

7. History of smoking and alcoholism

7.1 Smoking

7.2 Alcoholism

7.3 Both

7.4 No

8. Type of diet

8.1 Vegetarian

8.1 Non vegetarian

9. History of genito urinary diseases

9.1 Yes

9.2 No

10. History of cardiovascular diseases

10.1 Yes

10.2 No

11. History of hypertension

11.1 Yes

11.2 No

12. History of diabetes

12.1 Yes

12.2 No

APPENDIX - XI

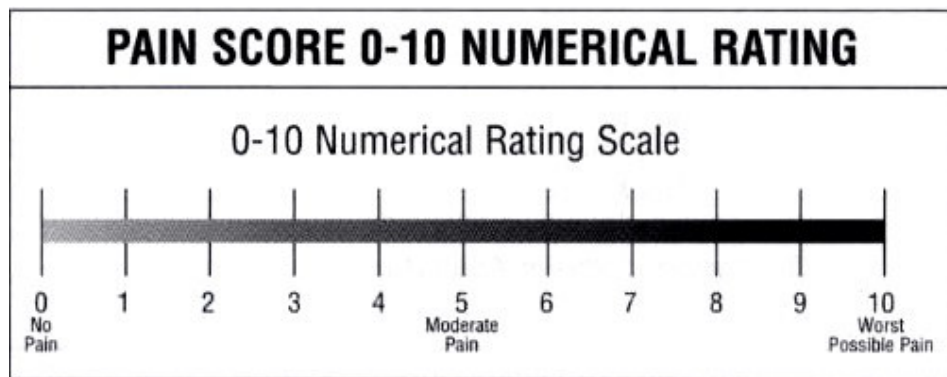
MODIFIED NUMERICAL PAIN RATING SCALE

Purpose

This scale is used to measure the muscle cramp intensity of the person receiving Hemodialysis before and after the intervention such as Intradialytic stretching exercise technique.

Instructions to participants

Please indicate how much pain you are feeling. This response will be kept confidentially.



SCORE	LEVEL OF PAIN
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

APPENDIX - XII

RATING SCALE ON LEVEL OF SATISFACTION OF PATIENT REGARDING INTRADIALYTIC STRETCHING EXERCISES DURING HEMODIALYSIS

Purpose

This questionnaire used by the researcher to know the level of satisfaction of intradialytic exercise among the patients receiving hemodialysis.

Instructions

This rating scale has got three categories and each question with four options which describe the level of satisfaction. Please answer the following questions and describe your satisfaction level about the intradialytic stretching exercise. Please feel free and frank in answering these questions. Confidentiality will be maintained.

S.no	Item	Highly satisfied	Moderately satisfied	Just satisfied	Dissatisfied
A.	About the method of intradialytic stretching exercise				
1.	Whether you were satisfied with the method of intradialytic stretching exercise				
2.	Are you satisfied with the duration of the exercise				
3.	Where you comfortable with the exercise				
4.	Are you satisfied with the timing of the exercise				

B.	About the effects of the exercise				
5.	Are you satisfied with the benefits of the exercise				
6.	Are you satisfied with the method of evaluation by the researcher				
C.	Researcher's approach				
7.	Where you comfortable with the approach of the researcher				
8.	Whether you satisfied with the methods of data collection				
9.	Are you satisfied with the method of communication by the researcher				
10.	Whether the explanation given by the researcher about the exercise was satisfactory				

SCORING KEY:

Highly satisfied - 4

Moderately satisfied - 3

Just satisfied - 2

Dissatisfied - 1

SCORING INTERPRETATION:

Highly satisfied > 75%

Moderately satisfied 50% - 75%

Just satisfied 25% - 50%

Dissatisfied < 25%

**BLUE PRINT OF RATING SCALE ON LEVEL OF SATISFACTION
OF PATIENT REGARDING INTRADIALYTIC STRETCHNING
EXERCISES DURING HEMODIALYSIS**

Item Description	Questions	No. of Questions	Percentage
About the method of Exercise	1, 2, 3, 4	4	40%
About the effect of the Exercise	5, 6	2	20%
About the researcher	7, 8, 9, 10	4	40%
Total		10	100%

APPENDIX XIII
DATA CODE SHEET

CONTROL GROUP	CG	Private	4
EXPERIMENTAL GROUP	EG	Business	5
Age in year	AG	Nature of work	NOW
20 -25	1	Sedentary	1
26-30	2	Moderate	2
31-35	3	Heavy	3
≥36	4	Height in cm	HT
Gender	GE	≤ 135	1
Male	1	136 -140	2
Female	2	140-145	3
Educational status	ES	146 – 15	4
No formal education	1	151 -155	5
Primary School	2	≥ 156	6
High school	3	Weight in kg	WT
Higher secondary	4	≤ 50	1
College and above	5	51-55	2
Occupation	OCC	56-60	3
Student	1	≥ 60	4
Unemployed	2	Temperature	WT
Government	3	96° - 97°F	1
		98° - 99°F	2
		99° - 100° F	3

Systolic Blood pressure	SBP	Both	2
≤100 mm hg	1	No	3
101-110 mm hg	2	Type of diet	TOD
111-120 mm hg	3	Vegetarian	1
121-130 mm hg	4	Mixed	2
≥131 mm hg	5	History of genito urinary diseases	FHOGUD
Diastolic blood pressure	DBP	Yes	1
≤ 60 mm hg	1	No	2
61-70 mmhg	2	History of cardiovascular diseases	FHOCVD
70-80 mm hg	3	Yes	1
≥81 mm hg	4	No	2
Type of Medication	TOM	History of hypertension	FHOHTN
Antibiotics	1	Yes	1
Analgesics	2	No	2
Others	3	History of diabetics	FHODM
History of smoking and alcoholism	HOS &A	Yes	1
Smoking	1	No	2
Alcoholism			

APPENDIX- XIV

EXPERIMENTAL GROUP MASTER CODE SHEET

SLNo	Demographic Variables										Clinical Variables										Pain Score		Level of satisfaction
	Age	Gd	Ed	Occ	Now	Ai	Ms	Hos &a	Tod	Fhogud	Fhocvd	Fhohtn	Fhodm	Ht	Wt	Tem	Sbp	Dbp	Tom	Prs	Pts		
1	3	1	4	4	2	1	1	3	1	2	1	1	2	3	2	2	3	3	3	8	1	35	
2	4	1	1	5	2	3	1	2	2	2	1	1	1	5	3	2	4	3	2	6	0	36	
3	3	2	5	2	1	1	1	4	2	1	2	1	2	6	2	2	4	4	1	6	1	34	
4	4	1	3	3	3	2	1	3	2	2	2	1	2	5	3	3	3	3	1	7	1	35	
5	2	2	1	4	3	2	1	4	2	2	1	1	1	6	4	3	4	3	3	9	1	35	
6	3	1	4	3	3	3	1	2	1	2	2	1	1	6	4	2	3	2	2	8	0	35	
7	3	2	2	5	2	1	1	4	2	2	1	2	2	6	3	2	5	2	3	5	0	37	
8	4	1	5	4	3	3	4	1	1	2	2	2	1	5	4	3	4	3	3	6	0	37	
9	4	1	1	4	2	2	1	3	2	1	2	2	2	6	3	3	4	4	2	8	2	37	
10	2	1	2	5	2	2	1	3	2	1	2	2	1	6	3	2	3	2	2	9	2	36	
11	3	1	4	4	1	3	1	2	2	2	2	2	2	6	3	2	5	3	1	6	0	36	
12	1	2	5	5	2	3	1	4	2	1	1	1	1	6	3	2	2	4	2	6	1	36	
13	3	2	2	5	2	1	1	4	2	2	1	2	2	6	4	3	3	2	3	6	2	38	
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15	4	2	3	3	3	2	2	4	1	2	2	2	2	6	3	3	4	4	2	5	1	39	
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17	3	1	3	4	2	2	1	2	2	1	2	1	2	6	3	3	5	4	2	8	1	39	
18	4	1	5	4	3	3	2	2	2	2	2	2	2	6	4	2	2	4	2	6	0	34	
19	3	1	2	5	2	2	1	2	2	2	1	2	2	6	3	2	3	3	2	7	1	35	
20	3	1	4	5	2	3	1	3	1	1	2	1	2	5	4	2	3	3	2	6	0	35	
21	4	2	2	2	1	1	1	4	2	2	2	1	2	6	3	2	3	2	3	7	0	34	
22	3	2	3	3	2	2	1	4	2	1	1	2	1	6	3	2	3	2	2	7	1	33	
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28	2	2	4	2	1	2	1	4	1	2	2	1	2	6	4	2	4	3	3	6	1	35	
29	1	2	5	4	3	2	2	4	1	2	1	1	2	6	4	2	4	3	2	6	1	35	
30	3	2	3	5	3	3	2	4	1	1	1	2	2	6	4	2	4	3	2	5	1	39	

CONTROL GROUP MASTER CODE SHEET

SLNo	Demographic Variables										Clinical Variables										Pain Score	
	Age	Gd	Ed	Occ	Now	Ai	Ms	Hos &a	Tod	Fhogud	Fhocvd	Fhohtn	Fhodm	Ht	Wt	Tem	Sbp	Dbp	Tom	Prs	Pts	
1	2	2	3	2	1	1	1	4	2	2	1	1	2	6	2	2	3	4	1	7	6	
2	3	2	3	3	2	1	1	4	1	1	1	2	2	6	2	2	4	3	3	9	7	
3	4	1	3	2	2	1	1	4	1	1	2	1	1	6	3	2	3	3	2	8	4	
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11	4	1	5	4	2	3	1	1	1	1	2	1	2	5	3	2	3	2	2	5	5	
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13	3	2	3	5	1	2	1	4	2	1	2	1	2	5	4	2	4	4	2	8	6	
14	3	2	4	4	2	2	1	4	2	2	2	2	2	5	3	2	3	4	2	8	7	
15	3	1	5	3	1	2	1	2	2	2	1	1	2	6	3	2	4	4	2	6	6	
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APPENDIX - XV

PHOTOGRAPHS DURING DATA COLLECTION

